"A COMPARATIVE EVALUATION OF THE EFFICACY OF RECOMBINANT HUMAN FIBROBLAST GROWTH FACTOR 2 (FGF-2) IMPREGNATED BIORESORBABLE COLLAGEN MEMBRANE AND BIORESORBABLE COLLAGEN MEMBRANE IN THE MANAGEMENT OF MILLER'S CLASS I & II GINGIVAL RECESSION – A RANDOMISED CONTROLLED STUDY."

Dissertation submitted to

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In partial fulfilment of the requirement for the degree of

MASTER OF DENTAL SURGERY

In the Specialty of

PERIODONTICS & ORAL IMPLANTOLOGY

By

Dr. Kavita Singh

Under the guidance of

Dr. Shivaani Sharrma

BDS, MDS

Professor and Head

DEPARTMENT OF PERIODONTICS AND ORAL IMPLANTOLOGY

SANTOSH DENTAL COLLEGE & HOSPITALS

GHAZIABAD- 201009, NCR DELHI, INDIA

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Date

Place:

Prof. Dr. Akshay Bhargava

MDS (Prosthodontics)

AFFAAID, DICOI, DWCOI

DEAN

Santosh Dental College and

Hospitals, Ghaziabad, NCR, Delhi

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Dr. Shivaani Sharrma

BDS, MDS

Professor & Head

Department of Periodontics & Oral Implantology

Santosh Dental College and Hospitals, Ghaziabad, NCR,

Delhi

Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

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GUIDE

Dr Shivaani Sharrma
BDS, MDS
Professor & Head
Department of Periodontics & Oral Implantology
ɔsh Dental College and Ho
Ghaziabad, NCR, Delhi

CO -GUIDE

Dr. Kumar Saurav Singh
MDS, Professor
Department of Periodontics & Oral Implantology
Santosh Dental College and Hospital Ghaziabad, NCR, Delhi

CO -GUIDE

Dr Amitabh Varshney
MDS, Reader
Department of Periodontics & Oral Implantology
Santosh Dental College and Hospital
Ghaziabad, NCR, Delhi

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Date:

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Dr. Kavita Singh

LIST OF ABBREVIATIONS

ABBREVIATIONS	FULL FORMS
GTR	**Guided Tissue Regeneration**
FGF 2	**Fibroblasts Growth Factor 2**
CAF	**Coronally Advanced Flap**
PDL	**Periodontal Ligament**
RD	**Recession Depth**
WKG	**Width of Keratinised Gingiva**
CAL	**Clinical Attachment Level**
PPD	**Probing Pocket Depth**
GB	**Gingival Biotype**
PI	**Plaque Index**
GI	**Gingival Index**
SRP	**Scaling and Root Planing**
UNC-15	**University of North Carolina-15**

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INTRODUCTION

INTRODUCTION

Gingival recession (GR) is a frequently encountered condition affecting the periodontal tissues, often linked to both esthetic and functional concerns.[1] It is the movement of the gingiva from the margin in an apical direction beyond the CEJ.[2] According to the AAP 2017 classification, it is an apical shift of the gingival margin caused by different pathologies. It is related with clinical attachment loss. All surfaces (lingual, buccal, and interproximal) may be affected by this.[3]

An array of predisposing and modifiable factors influence the onset of gingival recession.[4] Key predisposing elements include a delicate or thin gingival biotype, narrow band (<2mm) or absence of keratinised gingiva, probing pocket depths that extends past the mucogingival junction, and a personal history of either advancing gingival recession or inflammatory periodontal conditions. On the other hand, several modifiable factors can exacerbate the conditions. These include the accumulation of dental plaque, inflammatory periodontal disease, abnormal frenal attachments, anatomical soft tissue anomalies, improper or forceful oral hygiene practices, reduced vestibular depth, orthodontic movements of teeth, restorations that extend beneath the gingiva, tobacco use, and systemic health issues like diabetes.[4-5] It is essential for clinicians to recognise these factors and intervene accordingly. Moreover, the implementation of effective treatment protocols and education can significantly enhance patient understanding and help mitigate the risk of progression of gingival recession.[5,6]

Root covering techniques depend on tissue displacement, either by free gingival or connective tissue graft or translation (pedicle flap procedures), using non-resorbable as well as resorbable membranes in line with concepts of GTR (guided tissue regeneration).[7] It is advised to use pedicle flap surgical techniques (coronally advanced flap, initially introduced in 1926 by Norberg)[8] under conditions of appropriate keratinized tissue near recession defect. The cornerstone for treating gingival recession is a connective tissue graft combined with coronally advanced flap to cover the graft, out of all the surgical techniques used to cure gingival recession.[7,9,10,11]

GTR is the process by which PDL (periodontal ligament) cells helps to regenerate periodontal tissue by means of an occlusive barrier membrane.[12,13,14] The role of PDL cells on root surface was first described by *Pini Prato et al*[15] which possibly aid in regeneration of new bone as well as cementum, thus barrier membranes were used in root covering operations. This strategy allows slower-moving mesenchymal cells to colonize the area in place of epithelial cells, which migrate apically too quickly. Although the long junctional epithelium's ability to mend effectively protects against local inflammation, the GTR-based root covering technique has the benefit of reestablishing the natural attachment mechanism, which improves stability over the long run.[16] A perfect GTR membrane should meet certain criteria, namely being biocompatible so that it may integrate

with the host tissues without causing inflammation.[17] Its degradation profile should be appropriate for the four to six weeks needed for tissue regeneration. After serving its role, the membrane should ideally completely dissolve, leaving no materials behind.[18] To achieve proper cell development and proliferation, the membrane needs to be porous, and the cells themselves need to have a high-pore structure underneath.[19] To avoid external mechanical disruptions and flap movement overhanging throughout the healing process, the membrane needs to be stable. A GTR membrane should have a strict framework and be clinically manageable by the physician.[17] It can be utilized to separate various kinds of undesirable tissue (such as epithelial cells) and gain access to the place of interest (cell exclusion).[20]

Barrier membranes are generally divided into three generations of membranes. Non-resorbable guided membranes are first generation of membranes. First generation of barrier membranes were created in the 1960s and 1970s with the intention of producing a less harmful reaction in the host while simultaneously obtaining sufficient mix of physical characteristics that would match those of replaced tissue.[12,14] Two such membranes are e-PTFE (expanded polytetrafluoroethylene) and high-density d-PTFE. To reduce drawbacks of first-generation membranes, most notably requirement for a secondary surgical procedure to retrieve the membrane, second-generation membranes, which are resorbable guided membranes such as Epi-Guide and Bio-Gide®.[12,14] Third-generation membranes are those that have a more sophisticated function as a barrier membrane and may also release growth factors, adhesion factors, antibiotics, and bio-ceramic beneficial chemicals into the wound. e.g., membrane with nano-carbonated hydroxyapatite (nCHAC), antibiotic-loaded membranes.[12,19]

In soft tissue repair and periodontal regeneration, growth factors are essential, especially during root covering operations. rhPDGF-BB (recombinant human platelet derived growth factor) is third-generation membrane that has shown great promise in improving periodontal health and fostering soft tissue regeneration in both clinical and histological settings. In addition to promoting the regeneration of soft tissues to adequately cover exposed root surfaces, growth factors work in tandem with a collagen membrane to help change a thin gingival biotype into a thicker, more durable biotype. According to a recent review, growth factors may promote the regeneration of soft tissues, including the restoration of mucogingival architecture as well as the regeneration of periodontal soft and hard tissues, involving cementum, bone, periodontal ligament fibers.[21,22] The ability of FGF-2 (fibroblast growth factor-2) to effectively promote soft tissue covering and improve periodontal regeneration has drawn attention recently.

A vast family of structurally related proteins, involving FGF-2, influences growth, differentiation, migration, and survival of many different types of cells. In addition to having structural similarities with other FGF family

members, all of these growth elements bind to heparan and heparin sulfate, which boosts proliferation of undifferentiated mesenchymal cells and promotes robust angiogenic activity. FGF-2 encourages osteoblasts and fibroblasts to proliferate. These actions have a direct connection to regeneration of periodontal tissue. Nonetheless, since periodontal ligament cells are known to be significant for regeneration of periodontal tissue, these roles can be applied to membranes impregnated with FGF-2, which stimulates formation of bone as well as cementum and has a greater capacity to support periodontal regeneration in recession defects.[21,22]

In light of the limited research available exploring the combined use of FGF-2 and collagen membranes, this research was undertaken to evaluate and compare the clinical efficacy of bioresorbable collagen membrane alone versus collagen membrane infused with recombinant human FGF-2 for treating Miller's Class I and II recession defects.

AIM AND OBJECTIVES

AIM AND OBJECTIVES

AIM

To evaluate and compare the efficacy of a bioresorbable collagen membrane impregnated with recombinant human fibroblast growth factor-2 (FGF-2) and a plain bioresorbable collagen membrane in managing Miller's Class I and II gingival recession defects.

PRIMARY OBJECTIVES

To evaluate and compare: -

- The changes in recession depth (RD) within and between the two groups i.e. recombinant human fibroblasts growth factor 2(FGF 2) impregnated bioresorbable collagen membrane with bioresorbable collagen membrane alone at baseline, 3 months, and 6 months post-surgery.
- Changes in terms of gain in width of keratinised gingiva (WKG) within & between the two groups at baseline, 3 months and 6 months post-surgery.
- Clinical attachment level (CAL) within and between the two groups at baseline, 3 months and 6 months post-surgery.
- Probing pocket depth (PPD) within and between the control and test group at baseline, 3 months and 6 months post-surgery.
- Gain in gingival biotype (thickness) within and between the groups at baseline, 3 months and 6 months post-surgery.

SECONDARY OBJECTIVES

To evaluate and compare:

- Plaque index (PI) and Gingival index (GI) at baseline, 3 months and 6 months post-surgery within and between the two groups.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

The ultimate goal of treatment of gingival recession is to restore the tissue margin to the CEJ and to create a normal gingival sulcus with functional attachment. Over the years various surgical procedures have been used in the treatment of these defects. However, GTR is a commonly used treatment modality aimed at guiding & achieving regeneration and various resorbable membrane can be used to achieve the same. Hereby quoting few studies in which GTR has been used to cover the gingival recession defects.

Yang Y, Ouyang L, Cao C, Yan Y, Cheng Q, Jin B (2025)[23] This systematic review and meta-analysis evaluated the effectiveness of using concentrated growth factor (CGF) in combination with the coronally advanced flap (CAF) technique for treating gingival recession (GR). Analyzing eight randomized controlled trials involving systemically healthy adults with Miller Class I/II or Cairo RT1 recessions, the study found that CAF + CGF significantly improved clinical outcomes compared to CAF alone. Improvements were noted in complete root coverage (CRC), mean root coverage (MRC), keratinized tissue width (KTW), gingival thickness (GT), and clinical attachment level (CAL). While CAF + connective tissue graft (CTG) was superior in achieving complete root coverage compared to CAF + CGF, no significant differences were observed between CAF + CGF and CAF + CTG in other parameters. Similarly, CAF + CGF showed outcomes comparable to CAF + platelet-rich fibrin (PRF). CAF combined with CGF enhances outcomes over CAF alone and presents a promising alternative to CTG when graft harvesting is not feasible.

Ruiz-de-Gopegui-Palacios E, Vilor-Fernández M, García-De-La-Fuente AM, Marichalar-Mendía X, Aguirre-Zorzano LA (2024)[24] In this randomised double- blind clinical trial the study aimed to evaluate the clinical efficacy of treating RT2 gingival recessions using a xenogenic collagen matrix (CMX) in combination with a coronally advanced flap (CAF) compared to the gold-standard connective tissue graft (CTG) with CAF. Results showed that the connective tissue graft (CTG) group achieved a significantly greater mean root coverage (MRC) of 69.72% compared to 56.48% in the collagen matrix (CMX) group, along with slightly better complete root coverage (CRC) rates (40% vs. 35%). However, patients treated with CMX experienced notably less postoperative pain and required shorter surgical time (41 minutes versus 49.15 minutes). Aesthetic outcomes and patient satisfaction were similar in both groups, as evaluated by clinicians and patients alike. These results indicated that although CTG remains more effective for root coverage, CMX serves as a promising alternative, particularly in cases where minimizing surgical time and patient discomfort is a priority.

El Serafy MEH, El Razzak MYA, Shoukheba MYM, Ghouraba, RF (2024)[25] evaluated the effectiveness of a growth factor-enhanced matrix (GEM 21s) combined with either a free connective tissue graft (CTG) or a collagen membrane (CM) in treating Miller Class II gingival recession. Both groups showed significant clinical improvement, but the GEM + CTG group demonstrated superior outcomes in root coverage, keratinized tissue gain, and bone regeneration. The findings suggested that GEM 21s with CTG was more effective than with CM for periodontal regeneration.

Rampalli VC, Kandikatla R, Kidambi S, Vallabhdas S, Aileni RA (2023)[26] In this study the regenerative potential of rhFGF-2 impregnated collagen membranes was assessed in sites with multiple gingival recession defects. FGF-2 sites showed significant (3.88±0.33 vs 3.34±0.51; p=0.04) increase in WKG from baseline to 3-months and 6-months respectively over C-group sites. At 6-months, FGF-2 sites showed highly significant (1.38±0.99 vs 2.13±0.62; p≤0.001) decrease in RD as well. rhFGF-2 impregnated collagen scaffolds seem to confer additional benefits over plain collagen membranes in terms of recession coverage and healing following mucogingival procedures.

Pradhan S, Shetty N, Kamath N (2022)[27] conducted randomised controlled trial in which CAF+CM (Collagen membrane) was performed on one side whereas CAF+CTG (Connective tissue graft) was performed on the other side. The gingival thickness of the CAF+CM group increased significantly at three and six months.

Potharaju SP, Prathypaty SK, Chintala RK, Kumar DS, Bai YD, Bolla VL et al (2022)[28] This split-mouth clinical study evaluated the comparative efficacy of coronally advanced flap (CAF) alone versus CAF combined with a resorbable Type I collagen membrane for the treatment of Miller's Class I and II gingival recession defects. Thirty sites from fifteen patients were divided into two groups: Group A received CAF alone, and Group B received CAF with a bovine-derived, FDA-approved bioabsorbable Type I collagen membrane. After 6 months, both groups showed significant improvements in clinical parameters such as recession depth, width, and clinical attachment level. The mean root coverage achieved was 73.13% in the membrane group and 71.60% in the non-membrane group, with no statistically significant difference between them. Although the use of the collagen membrane did not enhance clinical outcomes compared to CAF alone, both approaches were effective in achieving root coverage. The membrane used had a resorption time of 4–8 weeks, sufficient to support early wound healing.

Chandra RV, Sneha K, Pushpalatha S, Chakravarthy Y (2020).[21] reported in first human clinical trial, role of growth factor FGF-2 impregnated bioresorbable collagen membrane in the treatment of Miller's Class I& II gingival recession. They demonstrated clinically significant root coverage along with increased in width of keratinized gingiva and achievement of thick biotype.

Agarwal M, DhruvaKumar D (2019)[1] reported a case series on coronally repositioned flap with bioresorbable collagen membrane for miller's class I and class II recession. They included eight non-smoking healthy subjects with miller's class I and class II recession defects in the maxillary anterior region. Clinical variables included the recession depth, recession width, width of keratinized tissue, and width of attached gingiva at baseline, 3 months postoperatively. Results have shown significant root coverage reduction in the recession depth and width and also significant increase in width of keratinized tissue and attached gingiva. They concluded coronally repositioned flap with bioresorbable collagen membrane demonstrated good result in term of root coverage and increase in width of keratinized tissue.

AlSarhan M, Alnassar T, AlMuflehi N, Alotaibi D, Al-Mubarak S, Sukumaran A, et al. (2019)[29] evaluated the efficacy of xenogeneic collagen matrix (CMX) compared to connective tissue graft (CTG) in treating multiple adjacent gingival recessions (MAGRs). The analysis included four randomized controlled trials assessing parameters such as recession depth, complete root coverage (CRC), mean root coverage (MRC), probing depth, clinical attachment level, and keratinized tissue width. Results indicated that CMX achieved significantly lower CRC and MRC than CTG ($p = .001$), while recession width showed no significant difference between the two groups ($p = .203$). Although CMX demonstrated a significantly lower probing depth ($p = .023$), there were no significant differences in clinical attachment level ($p = .060$) and keratinized tissue width ($p = .052$) between the groups. Due to heterogeneity among the included studies, definitive conclusions regarding the noninferiority of CMX compared to CTG could not be drawn, highlighting the need for further long-term research to establish the relative efficacy of CMX in MAGR treatment.

Mishra P, Dhruvakumar D (2018)[30] reported a case of the use of type I collagen membrane to treat the isolated class I gingival recession. The membrane was shown to be integrated within the recipient connective tissue and good results were obtain with increase in gingival thickness and keratinized tissue width.

George KA, Dalvi BV, Cherian AS, Verghese R (2018)[31] This in vitro study compared the resorption rates of bovine collagen membrane and human amnion membrane, both of which are potential alternatives to autogenous connective tissue grafts in root coverage procedures. Membrane strips were tested over four weeks in phosphate buffer solution. Results showed that the amnion membrane retained its structure up to the third week and degraded 70% by the fourth week, while the bovine collagen membrane degraded faster, with 80% resorption by the fourth week, and more rapid degradation between the second and third week. The findings highlight that both membranes maintain their integrity for at least 2–3 weeks, which aligns with the critical early period of periodontal healing. However, amnion membrane demonstrated slightly slower resorption, suggesting its potential for

prolonged support during tissue regeneration. The study emphasizes that understanding membrane degradation time is essential, as sustained membrane presence aids in guided tissue regeneration and optimal clinical outcomes.

Mahajan R, Khinda P, Shewale A, Ghotra K, Bhasin MT, Bhasin P (2018)[32] compared the clinical effectiveness of placental membrane and Healiguide™ collagen membrane in treating Miller's Class I and II gingival recession using guided tissue regeneration. Both membranes showed significant improvements in root coverage and clinical attachment level (CAL), with the placental membrane demonstrating slightly better outcomes. The study concluded that placental membrane is a viable, biologically active alternative to conventional collagen membranes for periodontal regeneration.

Kapare K, Gopalakrishnan D, Kathariya R, Tyagi, T, Bagwe S (2016)[33] conducted a split-mouth study (bilateral buccal recession defects) to evaluate efficacy of the novel collagen membrane for root coverage of miller's class I and class II recession in the maxillary anteriors and premolars. 15 test (CAF+ membrane) and 15 control (CAF alone) sites were included. Clinical parameters included in the study were gingival recession depth (RD), probing pocket depth (PPD), clinical attachment level (CAL), and keratinized tissue height (KTH), which were measured at baseline and 9 months postoperatively. Results show that both test and control groups showed statistically significant reductions ($P < 0.05$) in RD ((1.54 ± 0.46 mm and 1.60 ± 0.07 mm), PPD (0.53 ± 0.15 mm and 0.94 ± 0.10 mm), increase in KTH (0.67 ± 0.90 mm and 0.73 ± 0.14 mm) when comparing the 9-month data from baseline. They concluded that there were no statistically significant differences between groups for RD, PPD, KTH and CAL.

Cha JK, Sun YK, Lee JS, Choi SH, Jung UW (2016)[34] investigated the use of fibroblast growth factor-2 (FGF-2) with porcine collagen matrix (CM) for root coverage in dogs. The FGF-2 group showed better early healing and significantly more cementum formation at 16 weeks compared to CM alone. While histologic outcomes were improved, complete root coverage did not differ significantly, suggesting FGF-2 enhances regeneration but may not impact full clinical coverage.

Gupta P, Gupta H (2014)[35] compared and evaluated the clinical outcome of the envelop type of coronally advanced flap (CAF) alone versus envelope type of coronally advanced flap with and without type I collagen membrane (NEOMEM) in the treatment of multiple buccal gingival recessions in a split mouth study. The clinical parameter (recession depth, probing depth, clinical attachment level(CAL) and width of keratinized tissue were measured at base line, 3 months, 6 months. The results of the study showed that in comparison to Group A, there was a statistically significant increase in CAL (2.23 ± 0.75 mm, $P < 0.001$) and keratinized width (2.30 ± 1.06 mm) in Group B ($P < 0.001$).

Bhaskar N, Chhabra V (2013)[36] presented two cases treated with coronally repositioned flap with highly purified resorbable membrane for the treatment of Millers' Class II gingival recession. Clinical variables included dimensions of Gingival Recession (GR), probing depth (PD) and clinical attachment level (CAL) using a William's periodontal probe. The clinical parameters were similarly repeated at 3 months and 6 months post- operatively. The results revealed a considerable increase in gingival covering. They concluded that coronally repositioned flap combined with bilayer collagen membrane is a safe and effective method for the coverage of denuded root surfaces.

Thoma DS, Hämmerle CHF, Jung RE, Rubert M, Gernhardt CR, Müller HP (2011)[37] conducted an experimental study in minipigs to evaluate animal clinical and histological healing of a newly developed collagen matrix used in conjunction with a coronally advanced flap (CAF) for the treatment of Miller Class I gingival recession defects. The study showed that the collagen matrix promoted favourable clinical outcomes with significant root coverage and an increase in soft tissue thickness. Histologically, the collagen matrix was well-integrated into the host tissue, supporting connective tissue formation and vascularization without signs of chronic inflammation. The matrix maintained space beneath the flap, guiding tissue regeneration. These findings suggested that the new collagen matrix can be a viable alternative to connective tissue grafts, providing effective clinical and biological healing in the management of gingival recession.

Leknes NK, Evandro SA, Daniel E (2005)[38] compared coronally positioned flap with or without biodegradable membranes for Miller's Class I and II gingival recession. Clinical measurement (width of keratinized tissue, clinical attachment level, probing depth and apical extent of gingival recession) were recorded at baseline, 6 months, 12 months and 6 years. They concluded that though coronally positioned flap offers a simple and reliable treatment alternate as a root coverage procedure in class I and II recession defects however long-term outcomes stability is critically dependent on the continuous follow up with re-instruction for non-traumatic brushing habit.

Trombelli L, Minenna L, Farina R, Scabbia A (2005)[39] conducted a study to evaluate the mucogingival complex of guided tissue regeneration (GTR) treated gingival recession defects. 20 patients were recruited for the study. Recession depth (RD), probing depth, clinical attachment level (CAL), and width of keratinized gingiva (KG) were assessed immediately before surgery, at 6 months, 4 years and 10 years post-surgery. Results showed that recession depth (RD) measured 0.9 ± 0.6 mm at 6 months, increased slightly to 1.0 ± 1.3 mm at 4 years, and reached 1.3 ± 1.6 mm at 10 years. Clinical attachment level (CAL) was 1.9 ± 1.0 mm at 6 months, rising to 2.2 ± 1.4 mm at 4 years and 2.6 ± 1.6 mm at 10 years. The width of keratinized gingiva (KG) showed a significant increase post-surgery and remained stable over time. At the 10-year follow-up, there were no notable changes compared to the 4-year results. The author concluded that the results of the present study failed to demonstrate changes over time in terms of clinical

outcome achieved following GTR procedure in gingival recession defects over a period between 4 and10 years post-surgery.

Gurgan CA, Oruc AM, Akkaya M (2004)[40] conducted a study to evaluate whether the mucogingival junction reverts back to its original location following coronally advanced flap procedure over a 5 year follow up period. The coronally advanced flap technique was used to treat 13 systemically healthy individuals who had Miller class I buccal gingival recessions. The 5-year follow-up data showed that the coronally advanced flap procedure failed to keep gingival tissue in a coronal position, and that the observed movement of the mucogingival junction back to its original location was partially based on gingival margin apical movement.

Roccuzzo M, Bunino M, Needleman I, Mariano S (2002)[41] conducted a systemic review to assess the efficacy of periodontic plasticsurgery in attaining root coverage in the treatment of localized gingival recession. Following surgicalprocedures were considered Guided tissue regeneration (GTR), Free gingival graft (FGG), Connective tissue graft (CTG) and Coronally advanced flap (CAF). Statistically significant greater benefit was found for connective tissue graft compared with GTR in recession reduction. No difference was found in comparing either GTR with CAF for resorbable vs non resorbable barrier membrane.

Bunyaratavej P, Wang HL (2001)[42] this review article suggested that the resorption time varies widely depending on the collagen source, cross-linking methods, and composition. For instance, BioMend(formaldehyde cross-linked bovine collagen) resorbs in 6–8 weeks, while BioMend Extend lasts up to 18 weeks. Periogen and Paroguide membranes, processed from bovine and calfskin sources respectively, degrade in 4–8 weeks. BioGide, made from porcine dermis without cross-linking, demonstrates a prolonged resorption of around 24 weeks. Notably, BioBar, a non-cross-linked bovine tendon membrane, exhibits the slowest degradation with a resorption time of 6–8 months. These findings highlighted how cross-linking and collagen source significantly affect the longevity of barrier membranes, with more extensive cross-linking generally delaying degradation. Such variability allows clinicians to select membranes tailored to the healing needs of specific regenerative procedures.

Boltchi FE, Edward PA, William WH (2000)[43] has conducted a study to evaluate the efficacy and predictability of a bioabsorbable barrier in the treatment of human recession deformities using a single-step surgical technique. One hundred consecutive single and multiple contiguous Miller Class I, II, and III buccalrecession defects in 41 patients were treated using a bioabsorbable barrier and coronally advanced flap. Clinical data were collected immediately before surgery, three months later, and after aminimum of six months. It was concluded that the use of guided tissue regeneration in periodontal plastic surgery is highly predictable and esthetic root coverage can be obtained without

the need for a second surgical procedure or a second surgical site, making it an appealing alternative to traditionalgrafting techniques.

Amarante ES., Leknes NK (2000)[44] compared the clinical outcome of coronally positioned flap procedure with or without bioabsorbable membrane in the treatment of human gingival recession. Twenty patients were enrolled for the study and randomly divided 20 sites per group (group 1 – membrane group and group 2 – non-membrane group). Clinical parameters included were apical extent of the gingival recession, the width of the recession defect measured at the cemento-enamel junction (CEJ), and the width of keratinized tissue at the recession site as well as probing depth and attachment level which were examined at baseline, 3months and 6 months. Results showed a significant gain in root coverage and clinical attachment level in both groups with no significant difference. The reduction in recession width was significantly greater in the non-membrane group than membrane group. Probing depth had no significant difference. When patients were grouped as smokers (8) and non-smokers (12), no significant differences were revealed. They concluded that coronally positioned flap technique provides a predictable, simple and convenient approach for root coverage in Miller's class I and class II recession defects. They also mentioned there were no significant results following the placement of bioabsorbable membrane.

Shieh AT, Wang HL, Glickman NG, MacNeil LR (1997)[45] In this study for the treatment of gingival recession, guided tissue regeneration (GTR) techniques have demonstrated encouraging outcomes. The goal of this study was to see how effective a bioabsorbable collagen membrane might be in treating coverage gingival recession. The findings of this study indicated that a collagen membrane may be employed as a barrier device in GTR-based root covering operations. The study consisted of ten people with Miller Class Ior Class II deficits and 2.5 mm gingival recession, with significant gains in CAL and keratinized tissue width at 6mm post-operatively.

MATERIALS AND METHODOLOGY

MATERIALS AND METHODOLOGY

SOURCE OF DATA

This RCT was performed in the Department of Periodontics & Oral Implantology at Santosh Dental College, Ghaziabad. From a total of 30(n) individuals screened, only those meeting the specified inclusion and exclusion criteria were enrolled. Each participant was thoroughly informed about the procedural constraints and potential advantages, and documented consent was secured prior to the commencement of treatment. The study was accepted by Institutional Ethical Committee.

SAMPLE SIZE

Sample size was determined to be 24 sites, divided equally between two groups, using n Master 2.0 software. The study was designed with a statistical power of 80% and 95% confidence interval (CI).

STUDY DESIGN

This is a randomized controlled study. Since we have equal number of subjects in both the groups randomization was done using block randomization method and allocation concealment was done through sealed envelopes. Patient were randomly allocated into two groups-Group A and Group B.

- Group A (Control Group)- Coronally Advanced Flap (CAF) with bioresorbable collagen membrane. (Cologide^{TM})
- Group B (Test Group)- CAF with FGF-2 impregnated bioresorbable collagen membrane. (Pro-Tiss)

STUDY PERIOD:

The clinical evaluation was done at three time points: at baseline, 3 months and 6 months.

CRITERIA FOR CASE SELECTION

INCLUSION CRITERIA

- Individuals presenting with Miller's Class I and II gingival recession.
- Subjects exhibiting sufficient width of attached gingiva more than 2mm.
- Patients maintaining satisfactory levels of oral hygiene as assessed through plaque and gingival index

EXCLUSION CRITERIA

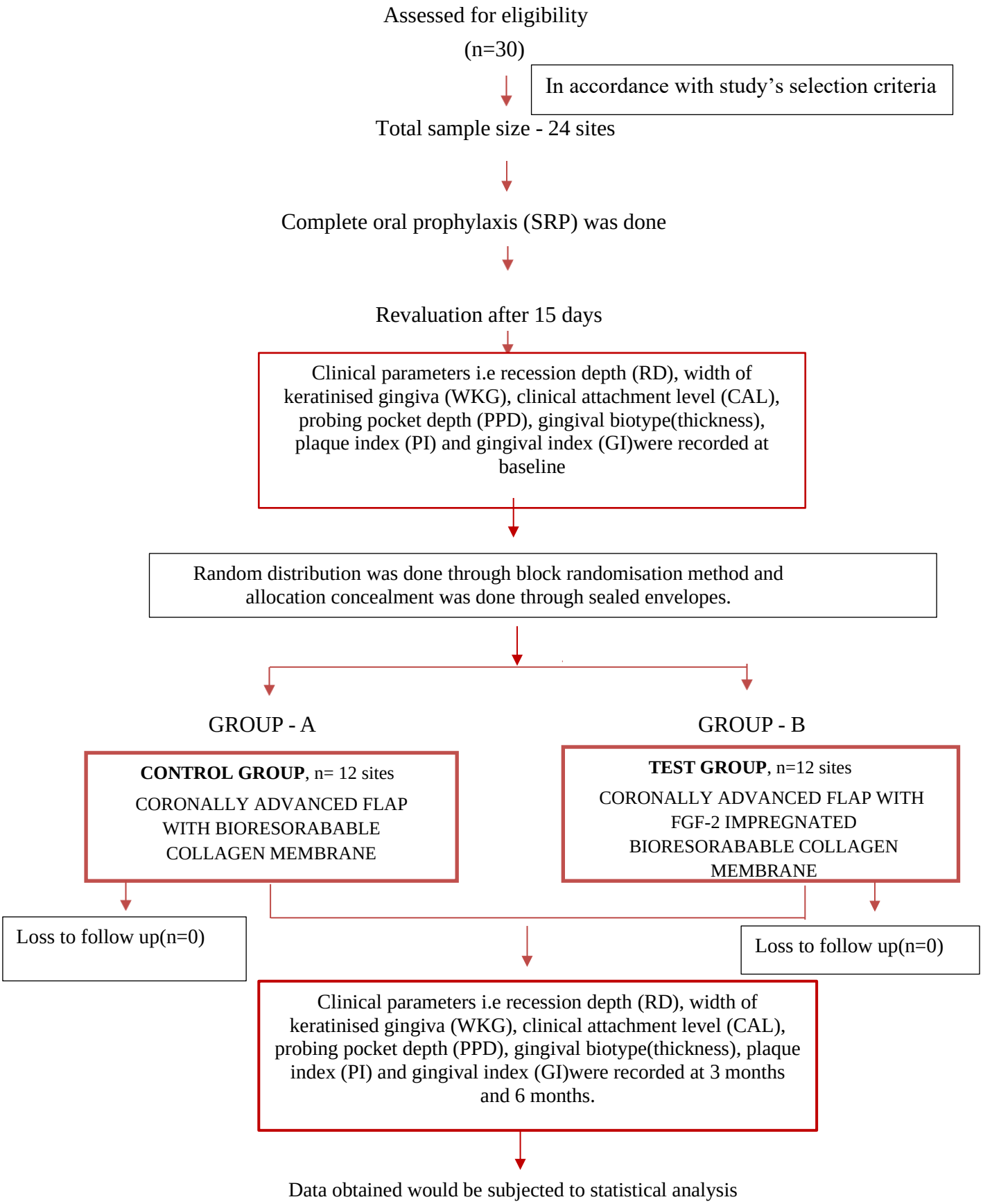
LOCAL

- Mal-aligned teeth.
- Active infection or inflammation in area of recession.
- Patients having trauma from occlusion.
- Absence of keratinised gingiva.
- Root caries.
- Patients who are not complying with oral hygiene instructions.

SYSTEMIC

- Smokers.
- Individuals with systemic conditions that could interfere with the study outcomes or any medical, physical or psychological factors that might impact the surgical intervention were excluded.

STUDY DESIGN


Assessed for eligibility
(n=30)
In accordance with study's selection criteria
Total sample size - 24 sites
Complete oral prophylaxis (SRP) was done
Revaluation after 15 days
Clinical parameters i.e recession depth (RD), width of keratinised gingiva (WKG), clinical attachment level (CAL), probing pocket depth (PPD), gingival biotype(thickness), plaque index (PI) and gingival index (GI)were recorded at baseline
Random distribution was done through block randomisation method and allocation concealment was done through sealed envelopes.
GROUP - A
GROUP - B
CONTROL GROUP, n= 12 sites
CORONALLY ADVANCED FLAP WITH BIORESORABABLE COLLAGEN MEMBRANE
TEST GROUP, n=12 sites
CORONALLY ADVANCED FLAP WITH FGF-2 IMPREGNATED BIORESORABABLE COLLAGEN MEMBRANE
Loss to follow up(n=0)
Loss to follow up(n=0)
Clinical parameters i.e recession depth (RD), width of keratinised gingiva (WKG), clinical attachment level (CAL), probing pocket depth (PPD), gingival biotype(thickness), plaque index (PI) and gingival index (GI)were recorded at 3 months and 6 months.
Data obtained would be subjected to statistical analysis

CLINICAL PARAMETERS

Clinical parameters were assessed at baseline (preoperatively), as well as at 3 and 6 months post-surgery. For consistency in measurements, an acrylic stent was fabricated for each patient and was used for recording the following parameters.

Recession Depth (RD): -

Calculation involved subtracting the distance between CEJ and stent, which was same for every instance during the trial, from the distance between the stent and the apical point of the free gingival margin.

Width of Keratinised Gingiva (WKG): -

Assessed at mid-buccal region by using a UNC-15 probe, the distance between the mucogingival junction and the free gingival margin. To determine the width, depth of gingival sulcus was subtracted from this measured distance

Probing Pocket Depth (PPD): -

Measurements were taken from the free margin of the gingiva to the base of the sulcus at the mesio-buccal, mid-buccal, and disto-buccal regions, using a UNC-15 probe, with readings rounded to the closest 0.5 mm

Clinical Attachment Level (CAL): -

Determined by measuring the distance from the cementoenamel junction (CEJ) to the base of the sulcus, using UNC 15 probe.

Gingival Biotype (Thickness): -

The mucosal surface was penetrated at 90 degrees with gentle pressure until hard tissue was reached under LA. A stopper on the reamer was adjusted until it was in close contact with gingiva. After the reamer was removed, the distance between the tip and the inner border of the silicon stopper was measured to nearest 0.5 mm.

Plaque Index (Silness and Loe, 1964)[46]: -

Plaque index was introduced by Silness J and Loe H in 1964. The scoring is done on the basis of selected tooth:

0- Absence of plaque.
1- A thin layer of plaque present on the free gingival margin and nearby tooth surface, often detectable only by gently passing a probe along the tooth surface.
2- Moderate level of soft deposits within the gingival pocket, on the gingival margin and/ or adjacent tooth surface, which can be observed without magnification.
3- Abundance of soft matter within the gingival pocket and/ or on gingival margin and adjacent tooth surface.

CALCULATION OF PI

The scores from four areas of the tooth are added and divided by four.

Interpretation

Excellent	0
Good	0.1-0.9
Fair	1.0-1.9
Poor	2.0-3.0

Gingival Index (Loe and Silness, 1963)[47] :-

Gingival index was introduced by Loe H and Silness J in 1963. The scoring is done on the basis of selected tooth:

0- Absence of gingival inflammation.

1- Slight inflammation, minimal change in color, mild edema, no bleeding upon probing.

2- Moderate inflammation, moderate swelling, glazing, redness and bleeding when probed.

3- Pronounced inflammation, evident redness, hypertrophy and ulceration, tendency for spontaneous bleeding.

CALCULATION OF GI

The scores from four areas of the tooth are added and divided by four.

Interpretation

Mild Gingivitis	0.1-1.0
Moderate Gingivitis	1.1-2.0
Severe Gingivitis	2.1-3.0

INVESTIGATIONS:

- Blood investigations-

Complete blood count (CBC) Clotting time (CT) Bleeding time (BT), Random blood sugar (RBS) and Glycated hemoglobin (HbA1c)

ARMAMENTARIUM

Diagnostic instruments: -

1. Mouth mirror
2. University of North Carolina (UNC-15) probe
3. Explorer
4. Pair of tweezers
5. Gloves
6. Mouth mask
7. Disposable syringe

Surgical Instruments

1. Bard –Parker handle
2. Bard –Parker Blades
3. Periosteal elevator
4. Goldman Fox scissors
5. Adams tissue holding forceps
6. Cotton swabs

7. Gauze strips
8. Dappen dish
9. Kidney tray with saline and irrigation syringe
10. Suture material
11. Suture cutting scissors
12. Needle holder
13. Universal curettes
14. Tissue retractors
15. Coe pack

Surgical Material

1. FGF-2 impregnated bioresorbable collagen membrane. (Protiss)
2. Bioresorbable collagen membrane (ColoGide^{TM})
3. Tetracycline capsules(250mg) for root conditioning.

METHOD

The participants were explained about the study's objectives, surgical procedure and its overall nature. A comprehensive case history was documented before initiating the surgical intervention

Pre-surgical Procedure:

All participants underwent a complete diagnostic assessment, which included:

1. Detailed case history followed by thorough oral prophylaxis.
2. Preparation of study models and clinical photographs.
3. Standard lab investigations like CBC, CT, BT, RBS, HbA1c.

Surgical Procedure:

1. Surgical site was anesthetized with 2% Lignocaine HCL with 1:80,000 Adrenalin. Coronally repositioned flap technique was done in both the groups.
2. Partial thickness flap was created via sharp dissection mesially and distally, joined by an intracrevicular incision. A full thickness flap raised apical to the recession on the facial surface to preserve maximum tissue for root coverage.
3. A horizontal incision 3mm apical to the bone was made to relieve muscle tension, followed by blunt dissection to allow coronal positioning of flap.
4. The tissue flap was repositioned coronally to the CEJ.
5. In Group A-following flap reflection, a bioresorbable collagen membrane will be trimmed, positioned, and sutured to cover the recession up to the CEJ.
6. In Group B-following flap reflection, FGF-2 impregnated bioresorbable collagen membrane will be trimmed,positioned, and sutured to cover the recession up to the CEJ.
7. The coronally advanced flap was placed over the membrane and suturing was done.
8. The surgical site was placed with periodontal pack.

POST-OPERATIVE CARE: As part of postoperative care, patients were asked to use 0.2% chlorhexidine gluconate twice daily and advised to follow Charters brushing technique. Analgesics and antibiotics were recommended for five days and advised was given to follow the routine post-operative instructions.The dressing as well as sutures were removed after 10 days post-surgery. Follow up was done at baseline, 3, 6 months.

COLOR PLATES

Figure 1: Clinical Armamentarium.

Figure 2: Bioresorbable Collagen membrane (Cologide^{TM})

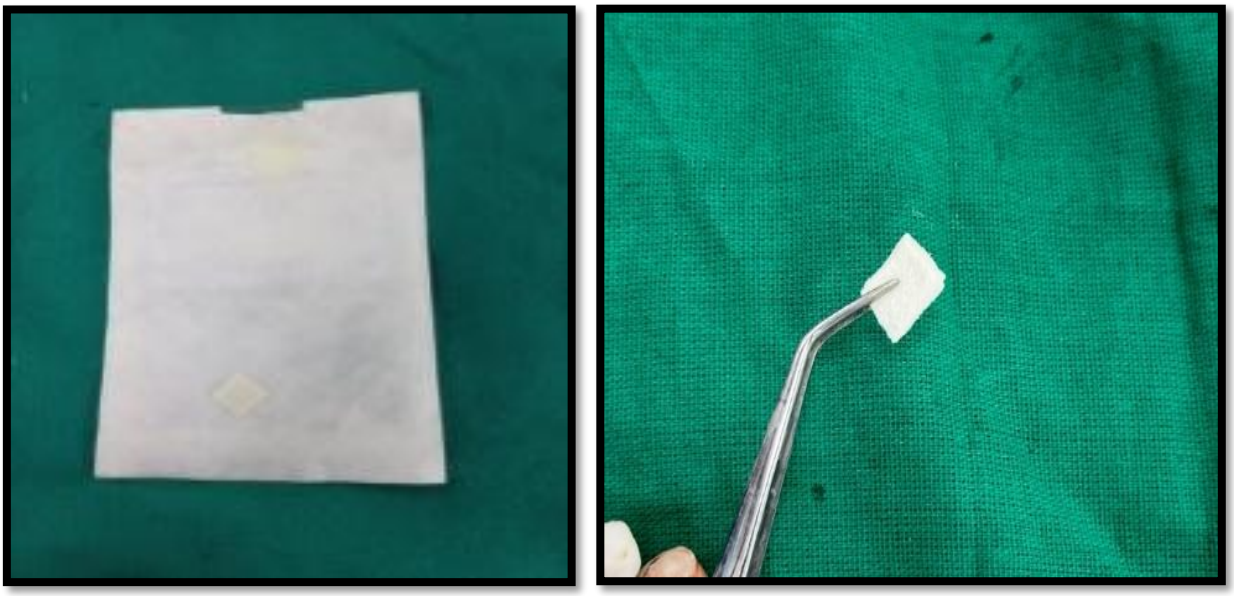


Figure 3: FGF-2 Impregnated Bioresorbable Collagen membrane (Pro-Tiss)

Figure 4: Tetracycline for Root Conditioning

CONTROL GROUP: PRE-OPERATIVE IMAGES AT BASELINE

Figure 5a: Recession Depth i.r.t. 11 at baseline

Figure 5b. Width of keratinized gingiva i.r.t 11 at baseline

Figure 5c: Probing pocket depth i.r.t.11 at baseline

Figure 5d: Gingival biotype i.r.t. 11 at baseline

CONTROL GROUP: SURGICAL IMAGES

Figure 6a: Incisions placed at surgical site

Figure 6b: Flap Reflection

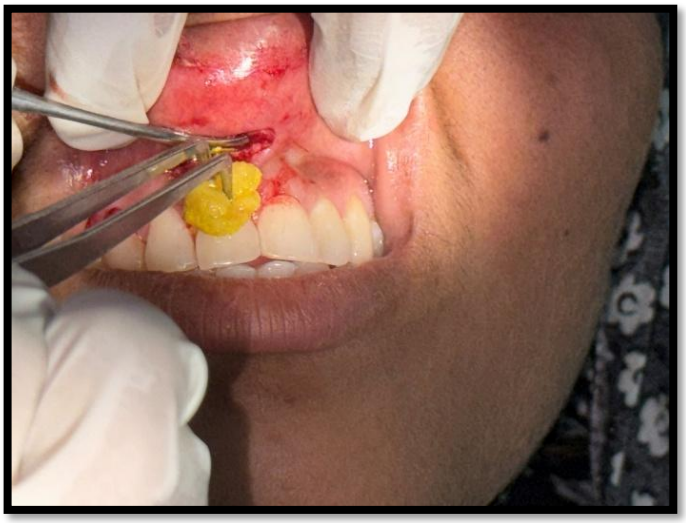


Figure 6c: Root conditioning with tetracycline

Figure 6d: Placement of collagen membrane

Figure 6e: Placement of suture

CONTROL GROUP: POST-OPERATIVE IMAGES 3 MONTHS POST-SURGERY

Figure 7a: Recession Depth i.r.t 11at 3 months post-surgery

Figure7b: Width of keratinised gingiva i.r.t 11 at 3 months post-surgery

Figure 7c: Probing pocket depth i.r.t 11 at 3 months post-surgery

Figure 7d: Gingival biotype i.r.t 11 at 3 months post-surgery

CONTROL GROUP: POST-OPERATIVE IMAGE 6 MONTHS POST-SURGERY

Figure 8a: Recession Depth i.r.t 11 at 6 months post-surgery

Figure 8b: Width of keratinised gingiva i.r.t 11 at 6 months post-surgery

Figure 8c: Probing pocket depth i.r.t 11 at 6 months post-surgery

Figure 8d: Gingival biotype i.r.t 11 at 6 months post-surgery

TEST GROUP: PRE-OPERATIVE IMAGES AT BASELINE

Figure 9a: Recession depth i.r.t. 23 at baseline

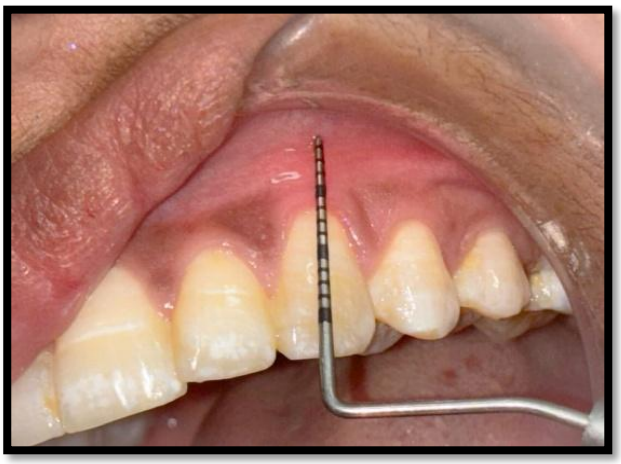


Figure 9b: Width of keratinised gingiva i.r.t. 23 at baseline

Figure 9c: Probing pocket depth i.r.t. 23 at baseline.

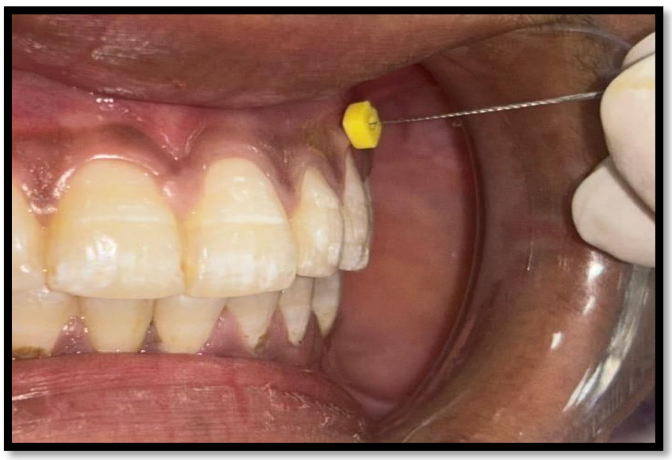


Figure 9d: Gingival Biotype i.r.t. 23 at baseline

TEST GROUP- SURGICAL IMAGES

Figure 10a: Incisions placed at the surgical site

Figure 10b: Flap reflection

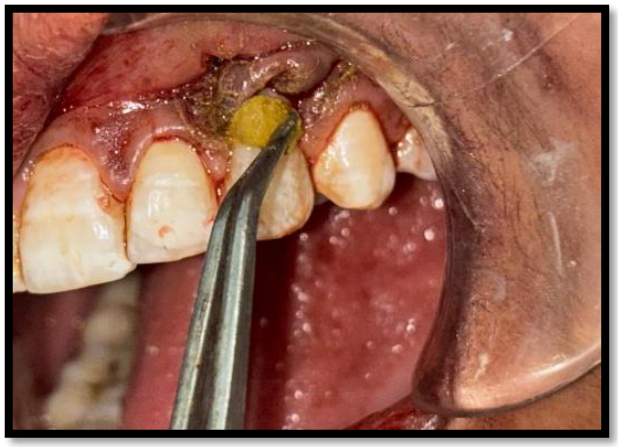


Figure 10c: Root conditioning with tetracycline

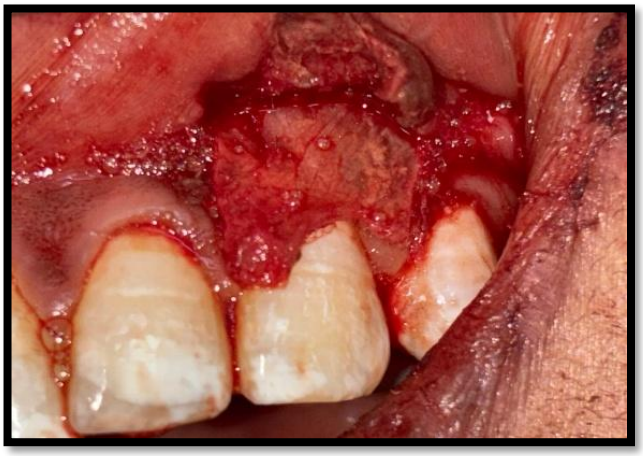


Figure 10d: Placement of FGF-2 impregnated collagen membrane

Figure 10e: Placement of Sutures

TEST GROUP: POST- OPERATIVE IMAGES 3 MONTHS POST-SURGERY

Figure 11a: Recession depth i.r.t. 23 at three months post-surgery

Figure 11b: Width of keratinised gingiva i.r.t. 23 at three months post-surgery

Figure 11c: Probing pocket depth i.r.t. 23 at 3 months post-surgery

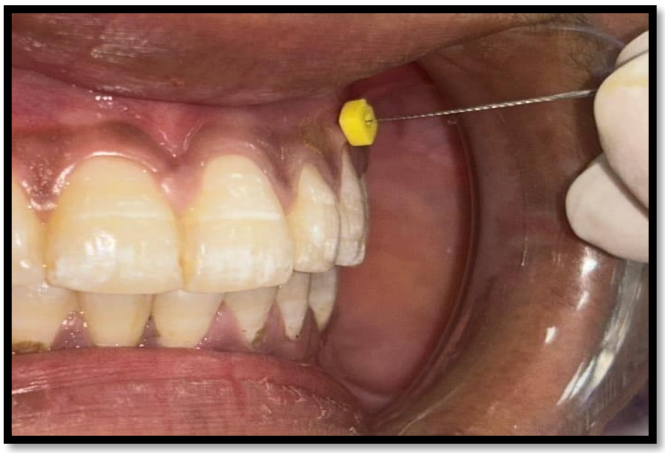


Figure 11d: Gingival Biotype i.r.t. 23 at 3 months post-surgery

TEST GROUP: POST- OPERATIVE IMAGES 6 MONTHS POST-SURGERY

Figure 12a: Recession depth i.r.t. 23 at 6 months post- surgery

Figure 12b: Width of keratinised gingiva i.r.t. 23 at 6 months post-surgery

Figure 12c: Probing pocket depth i.r.t. 23 at 6 months post-surgery

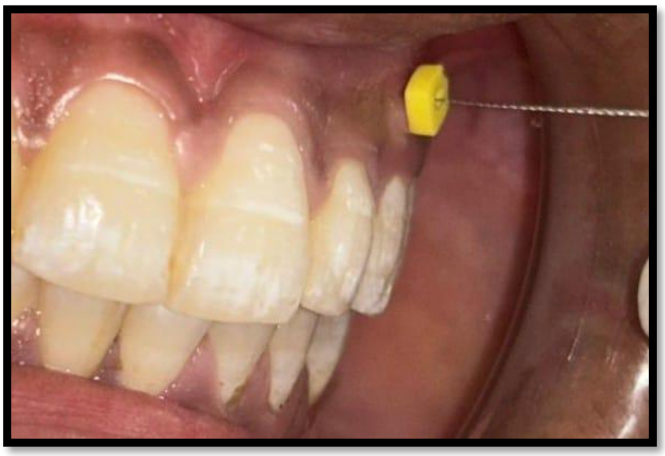


Figure 12d: Gingival Biotype i.r.t. 23 at 6 months post-surgery

STATISTICAL ANALYSIS

STATISTICAL ANALYSIS

Descriptive statistics was performed by calculating mean and standard deviation for the Continuous variables.

The data was entered into Microsoft Excel and analysed using **SPSS (Statistical Package for Social Sciences) package 26.0** for relevant statistical comparisons. Results was presented in the form of tables and graphs.

The statistical tests used were:

Shapiro Wilk test was used to check whether the continuous variables were following normal distribution or not.

The Non-parametric test Wilcoxon sign Rank test was used where the data does not follow the normal distribution.

Level of statistical significance was set at **p-value less than or equal to 0.05.**

The following formulas were employed for calculation for various parameters:

1. **Mean/ Average**

Mean or Average is defined as the sum of all the given elements divided by the total number of elements.

Mean = sum of elements / number of elements It is

denoted by the letter X.

$$X = \frac{\sum X}{\text{No. of observations (n)}}$$

2. **Standard Deviation**

The **standard deviation** of a statistical population, a data set, or a probability distribution is the square root of its variance. Standard deviation is a widely used measure of the variability or dispersion.

It shows how much variation there is from the **"Average" or "Mean"**. It is denoted by the **letter σ**.

For **Small samples, n<30**

$$SD = \sqrt{\frac{\sum (X - \bar{X})^2}{n-1}}$$

For **Large samples, n>30**

$$SD = \sqrt{\frac{\sum (X - \bar{X})^2}{n}}$$

3. Shapiro-Wilk Test

- The Shapiro-Wilk test was used for testing the normality (uniformity of the distribution of thedata) of the data. This approach is limited to samples between 3 and 50 elements.
- The basic approach used in the Shapiro-Wilk (SW) test for normality is as follows:
- Rearrange the data in ascending order so that $x_1 \leq \ldots \leq x_n$.
- Calculation of SS is as follows:

$$SS = \sum_{i=1}^{n} (x_i - \bar{x})^2$$

If n is even, let m = n/2, while if n is odd let m = (n–1)/2.

Calculate b as follows, taking the ai weights (based on the value of n) in the Shapiro-Wilk Tables.Note that if n is odd, the median data value is not used in the calculation of b.

$$b = \sum_{i=1}^{m} a_i (x_{n+1-i} - x_i)$$

Calculate the test statistic W = b2 ⁄ SS

- A non-significant test means the sample distribution is shaped like a normal curve (uniform distribution of the values around an average value or a measure of central tendency) and

Parametric test are to be used.

4. Wilcoxon Signed Rank Test

- The Wilcoxon Signed- Rank test is an non-parametric statistical test used to compare two related samples, measuring whether their population mean ranks differ.
- It is alternative to the paired t- test when the data does not follow a normal distribution.
- The formula to calculate is as follows:

$$Z = \frac{W - \frac{n(n+1)}{4}}{\sqrt{\frac{n(n+1)(2n+1)}{24}}}$$

Where W is test statistic : $W = \min(W+, W-)$
If the computed Z-value is **beyond the critical value** for a chosen significance level (p typically 0.05), **reject the null hypothesis**.

5. Level of Significance (p-value)

- The maximum probability of rejecting a correct null hypothesis.
- In testing a given hypothesis, the maximum probability with which we would be willing to take risk is called Level of Significance of the Test.
  - **P-value ≥ 0.05 – Non-Significant.**
  - **P-value < 0.05 – Significant.**
  - **P-value < 0.01 - Highly Significant.**
  - **P-value < 0.001 - Very Highly Significant.**

RESULTS

RESULTS

Patients with Miller's Class I and II gingival recession defects were selected from the Department of Periodontics & Oral Implantology, Santosh Dental College and Hospital, Ghaziabad, contributing 24 sites that were randomly allocated into two groups using block randomization method. Group A (Control Group) consisted of 12 sites treated with CAF along with bioresorbable collagen membrane alone while Group B (Test Group) consisted of 12 sites treated with CAF combined with recombinant human fibroblast growth factor 2 (FGF-2) impregnated bioresorbable collagen membrane. All patients underwent initial phase therapy including scaling and root planing (SRP), and an acrylic stent was fabricated for each patient to standardize clinical measurements. The following clinical parameters were recorded at baseline (post-SRP), 3 months, and 6 months: Recession Depth (RD), Width of Keratinized Gingiva (WKG), Clinical Attachment Level (CAL), Probing Pocket Depth (PPD), Gingival Biotype, Plaque Index (PI) and Gingival Index (GI) with measurements performed using a UNC-15 probe and gingival biotype assessed using an endodontic reamer.

CLINICAL MEASUREMENTS:

RECESSION DEPTH(RD)

INTERGROUP COMPARISON (Table1A, Graph 1)

The mean RD at **baseline** in the **group A was 3.50 ± .674 mm** and in **group B** was **3.42 ± .515 mm** was **non-significant (p=.737),** indicating comparable initial clinical status between the groups. At **3 months**, both groups demonstrated a **reduction in RD**, with the **Group A** showing mean of **2.42 ± 0.669 mm** and the **Group B** showing a mean of **2.25 ± .452 mm** although, the values were **statistically non-significant (p=.482).** By the end of **6 months**, **group A** showed decrease in RD **1.58 ± 0.793 mm** and **group B** exhibited a marked decrease in RD **0.92 ± 0.515 mm**, with the difference found to be **statistically relevant (p=0.026).**

INTRAGROUP COMPARISION (Table 1B)

The mean RD in the **Group A** was **3.50 ± .674 mm**. During the interval from baseline to the third month, reduction in RD was **1.08± .289 mm**, which was **non-significant** (*p* = **.557**). Between baseline and 6 months the mean RD reduction was **1.50 ± 0.674mm.** This change from baseline was found to be **statistically meaningful (p = .026).** From 3 to 6 months, the mean RD reduction was **0.84± 0.515 mm** which was **statistically non-significant (0.096)**.

At **baseline**, the mean RD in the **Group B** was **3.42 ± 0.515 mm**. Between **baseline and 3 months**, RD was **1.17± 0.389 mm**, which was statistically insignificant (*p* = **.557**). From a period of baseline and 6 months the mean RD reduction was **1.92 ± 0.515mm**. This change from baseline was **statistically meaningful** (*p* = **.026**). From 3 to 6 months, the mean RD reduction was **1.33± 0.651 mm** which showed no significant difference**(p=.096)**.

WIDTH OF KERATINISED GINGIVA(WKG)

INTERGROUP COMPARISON (Table 2A, Graph2)

The mean WKG at **the start of the study in the control subjects** was **2.00 ± .739 mm,** and in the **test subjects was 2.42 ± .669 mm** which was slightly higher but the difference lacked statistical relevance**(p=.161)**, indicating a comparable starting point.

At **3 months**, **Group A** demonstrated WKG, **2.92 ± .793 mm**, and **Group B** showed a significantly higher mean WKG of **3.83 ± 0.937 mm**, with the difference being **statistically significant(*p*=.017).** After 6 months, the **group A** exhibited a mean WKG (3.08 ± .669 mm), while the **group B** showed a higher average WKG of **4.00 ± 0.603 mm,** with the difference reaching **statistically significant (p=0.002)**

INTRAGROUP COMPARISION (Table 2B)

In the **Group A**, the WKG was **2.00 ± 0.739 mm at the beginning of the study.** Between **baseline vs 3 months** the mean WKG increased by **0.92 ± 0.289 mm,** which showed significant value **(*p* = 0.035),** indicating that the control group showed measurable gain in gingival width during the first 3 months. Between **baseline vs 6 months** the mean gain in WKG was **1.08 ± 0.353 mm**, also statistically significant **(*p* = 0.008),** suggesting continued improvement through 6 months. The mean change observed between 3 and 6 months was **0.16 ± 0.389 mm,** with a **p-value of 1.000**, suggesting **no statistically significant improvement** during this period.

At baseline, the average WKG in the **test group** was **2.42 ± .669 mm**. By 3 months, there was a significant increase of **1.42 ± .619 mm** (*p* = **.026**), indicating a marked improvement during the early healing phase. This gain continued through 6 months, with the WKG increasing by **1.58 ± 0.515 mm** from baseline (*p* = **0.008**), confirming a sustained enhancement. However, the change between 3 and 6 months was only **0.17 ± 0.369 mm** (*p* = **1.000**), indicating **non- significant difference** during the period.

At baseline, the mean WKG in the **test group** was **2.42 ± 0.669 mm**. By 3 months, there was a statistically significant increase of **1.42 ± 0.619 mm** (*p* = **0.026**), indicating a marked improvement during the early healing phase. This gain continued through 6 months, with the WKG increasing by **1.58 ± 0.515 mm** from baseline (*p* = **0.008**), confirming a sustained enhancement. However, the change between 3 and 6 months was only **0.17 ± 0.369 mm** (*p* = **1.000**), indicating that there was no statistically significant difference observed during this period.

CLINICAL ATTACHMENT LEVEL(CAL)

INTERGROUP COMPARISON (Table3A, Graph 3)

The mean CAL at baseline was slightly greater in the **Group A** (**5.42 ± 1.505 mm**) when compared to the **Group B** (**4.83 ± 0.577 mm**), No meaningful difference was observed(*p*=**0.223**).

After 3 months, **both groups showed similar improvement**, with the **Group A** at **4.08 ± 0.900 mm** and

the **Group B** at **4.00 ± .426 mm**, and difference remained **non-significant** (*p* = **0.775**).

However, at 6 months, the **Group A** reached a mean CAL of **3.00 ± .953 mm**, while the **Group** B showed a significantly greater improvement, achieving a mean CAL of **2.33 ± 0.492 mm**, with the difference proving to be **statistically notable (p=.043).**

INTRAGROUP COMPARISON (Table 3B)

The **control group** had a CAL of **5.42 ± 1.505 mm at the start of the study**. When comparing the baseline to the 3-month, a mean gain of **1.34 ± 0.888 mm was seen**, however this improvement was statistically non-significant (*p* = **.088**). By the end of the study**, group B** showed a more pronounced and **statistically notable improvement** in CAL, with an average gain of **2.42 ± 1.165 mm** (*p* = **.037**), indicating effective periodontal healing over time. In contrast, the change observed from 3 to 6 months was **1.08 ± 1.084 mm**, but this difference was **not statistically meaningful (p = .104),** suggesting that the most of CAL gain occurred during the 3 months period, with a moderate, non-significant improvement afterward.

The **test group** showed baseline CAL of **4.83 ± .577 mm**. By 3 months, it showed a mean gain of **.83 ± .389 mm**, which, like the **control group,** was non-significant (*p* = **.088**). Across the baseline to 6-month interval, the test group demonstrated a **statistically significant improvement**, with a mean gain in CAL of **2.50 ± .522 mm** (*p* = **0.037**). Between 3 and 6 months, the test group showed an additional gain of **1.67 ± 0.492 mm**, however it was **non-significant** (*p* = **.104**)

PROBING POCKET DEPTH(PPD)

INTERGROUP COMPARISON (Table 4A, Graph 4)

Average PPD at baseline was higher in the **group A** (**1.92 ± .996 mm**) compared to the **group B** (**1.42 ± 0.515 mm**), although, **no meaningful difference** was observed**(p=.137)**

After 3 months, the **control subjects** exhibited PPD of **1.75 ± .452 mm**, while the **test subjects** showed a similar mean of **1.73 ± 0.451 mm**, with **non- significant difference among the groups** (*p* =**1.000**).

After 6 months, **group A** recorded a mean PPD of **1.50 ± .522 mm**, and **group B** showed a slightly lower mean of **1.25 ± 0.420 mm**; but this was also **non-significant** (*p* = **.223**).

INTRAGROUP COMPARISON (Table 4B)

At baseline, **control group** had a PPD of **1.92 ± 0.996 mm**. Between baseline to 3 months, a slight reduction was seen in PPD by **.17 ± .835 mm**, but this change **lacked statistical relevance** (*p* = **.088**). Throughout the baseline to 6-month duration, the PPD reduced by **0.42 ± 0.793 mm**, which was of **no significant value** (*p* = **.338**). Intragroup comparison from 3 months to 6 months showed a further average reduction of **.25 ± .622 mm**, again **non-significant** (*p* = **.298**).

In the FGF-2 group, the baseline mean PPD was **1.42 ± 0.515 mm**. Between baseline to 3 months, there was a slight increase in PPD by **–0.33 ± 0.492 mm**, though this change did not reach **statistical significance (*p* = 0.088)**. Between baseline to 6 months, the FGF-2 group showed a small reduction of **.17 ± 0.389 mm**, which also lacked **significant relevance** (*p* = **0.315**). The change between 3 and 6 months was **0.48 ± 0.522 mm**, which did not achieve statistical importance (*p* = **.275**).

GINGIVAL BIOTYPE

INTERGROUP COMPARISON (Table 5A, Graph 5)

The mean gingival biotype score at **baseline** was superior in the **group B (1.33 ± 0.492 mm)** compared to the **group A (1.08 ± 0.289mm),** with the difference demonstrating **statistical relevance(*p*=.143).** After **3 months**, no significant changes were observed in either group, and the difference between the **group A(1.25 ± 0.306mm) and group B(1.30 ± 0.496mm)** remained **non-significant(p=.123)** However, by **6 months**, the **non-FGF-2 group** maintained relatively stable biotype score of **1.35 ± 0.452mm**, whereas the **FGF-2 group** showed a increase to **1.75 ± 0.520mm**, which demonstrated

statistical relevance(*p* = .042).

INTRAGROUP COMPARISON (Table 5B)

At the beginning, the average gingival biotype in **group B** was **1.33 ± 0.492mm**. From baseline to 3 months, the biotype showed a slight increase of **0.08 ± 0.210mm**, the change was **non-significant** (*p* = **.345**), indicating minimal improvement during the early healing period. From baseline to 6 months, there was a further increase of only **0.02 ± 0.452mm**, the change was **statistically relevant** (*p* = **.001**). The comparison between 3 and 6 months revealed an increase of **0.10 ± 0.335mm**, which was also **statistically significant** (*p* = **.001**).

At the beginning, the FGF-2 group showed average gingival biotype of **1.08 ± 0.492mm**. Between baseline and 3 months, the biotype increased by **0.22 ± 0.020mm**, though this change **statistically not relevant***(p***=0.345)**.From baseline to 6 months, a **significant improvement** was noted, with an increase of **0.38 ± 0.520mm**, and this change was **statistically meaningful** (*p* = **0.001**), showing the positive impact of the FGF-2 impregnated collagen membrane.

The period from 3 to 6 months also showed a notable improvement of **0.45 ± 0.492mm**, again **statistically meaningful** (*p* = **.001**).

PLAQUE INDEX

INTERGROUP COMPARISON (Table 6A, Graph 6)

The differences in mean value of PI of **control group (2.05± 0.507)** and **test group (2.33± 0.424)** at **baseline** was of **no significant validation (*p*=0.802).** At **3 months,** the difference in mean value of PI of **control group (1.72± 0.566)** and **test group (1.47± 0.609)** was of **no significant difference (p=0.076).** Furthermore at **6 months,** the difference in average value of PI of **control group (1.65±0.591)** and **test group (1.08± 0.280)** was found to be **statistically relevant (*p*=.002).**

INTRAGROUP COMPARISON (Table 6B)

At **baseline,** the mean PI in the **control group** was **2.05 ± 0.507**. Between **baseline and 3 months**, a

modest reduction in PI of **0.30 ± 0.566** was observed, and this change was **statistically significant (*p* = 0.02)**, indicating an early improvement in plaque control. From **baseline to 6 months**, the PI further reduced by **0.40 ± 0.591**, which remained **significant (*p* = 0.03),** suggesting a continued but modest improvement.

However, between **3 and 6 months**, the change was only **0.07 ± 0.526**, and was **non-significant (*p* = 0.123)**.

At **baseline,** the **test subjects** had a greater mean PI of **2.33 ± 0.424**. A substantial reduction of **0.86 ± 0.609** was noted from **baseline to 3 months**, which was **highly statistically relevant (*p* = .002),** indicating a strong initial response in plaque control.

From **baseline to 6 months**, the reduction became even more pronounced, with a mean change of **1.25 ± 0.280**, and this change was statistically relevant **(*p* = 0.001)**. A comparison over the interval from 3 to 6 months also showed a **statistically significant** reduction of **0.39 ± 0.012 (*p* = .001)**

GINGIVAL INDEX

INTERGROUP COMPARISON (Table 7A, Graph 7)

The differences in mean value of gingival index of **control group (2.89±0.399)** and **test group (2.69± 0.398)** at **baseline** was **non - significant (p=1.000).** At **3 months,** the difference in mean value of gingival index of **control group (1.81± 0.467)** and **test group (1.61± 0.645)** was **statistically non-significant (p =.147).** Furthermore at **6 months,** the difference in mean value of gingival index of **control group (1.64±0.683)** and **test group (1.53± 0.654)** was found to be **non-significant (p=.483)**

INTRAGROUP COMPARISON (Table 7B)

At baseline, the mean GI in the control subjects was **2.89 ± .399**, indicating moderate gingival inflammation. From baseline to 3 months, a **statistically significant reduction** of **1.08 ± 0.467** was

observed (p = **0.03**). However, from baseline to 6 months, the reduction in GI was **1.28 ± .683**, which lacked **statistical relevance** (p = **0.245**). Between 3 and 6 months, the control group showed a small yet **statistically significant** reduction of **0.17 ± 0.136** (p = **0.002**), indicating continued but limited improvement after the initial phase.

In the test subjects, the mean GI at beginning was **2.69 ± 0.398**. There was a **statistically significant decrease** of **1.08 ± 0.645** (p = **0.004**), from baseline to 3 months, mirroring the pattern seen in the group B. The reduction from baseline to 6 months was **1.16 ± 0.654**, but this change failed to demonstrate statistical significance (p = **.059**). Between 3 and 6 months, **group B** exhibited a **statistically significant** decrease in GI of **0.08 ± 0.082** (p = **0.005**), showing continued gingival health improvement over time.

TABLES AND GRAPHS

TABLES AND GRAPHS

Table 1A: Intergroup comparison of Recession Depth (RD) (in mm) of control and test group over a period of time

Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	3.50	.674	.737**``
	TEST	12	3.42	.515	
3 Months	CONTROL	12	2.42	.669	.482**
	TEST	12	2.25	.452	
6 months	CONTROL	12	1.58	.793	**.026***
	TEST	12	0.92	.515	

** Non-Significant difference
*Significant difference

Table 1B: Intragroup comparison of Recession Depth (RD)(in mm) of control and test group over a period of time

CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	3.5	.674	-	Baseline	12	3.42	.515	-
Baseline vs 3 months	12	1.08	.289	.557**	Baseline vs 3 Months	12	1.17	.389	.557**
Baseline vs 6 Months	12	1.50	.674	**.026***	Baseline vs 6 Months	12	1.92	.515	**.026***
3 months vs 6 months	12	.84	.515	.096**	3 months vs 6 months	12	1.33	.651	.096**

** Non-Significant difference
* Significant difference

Graph 1: Intergroup comparison of Recession Depth (RD) (in mm) of control and test group over a period of time

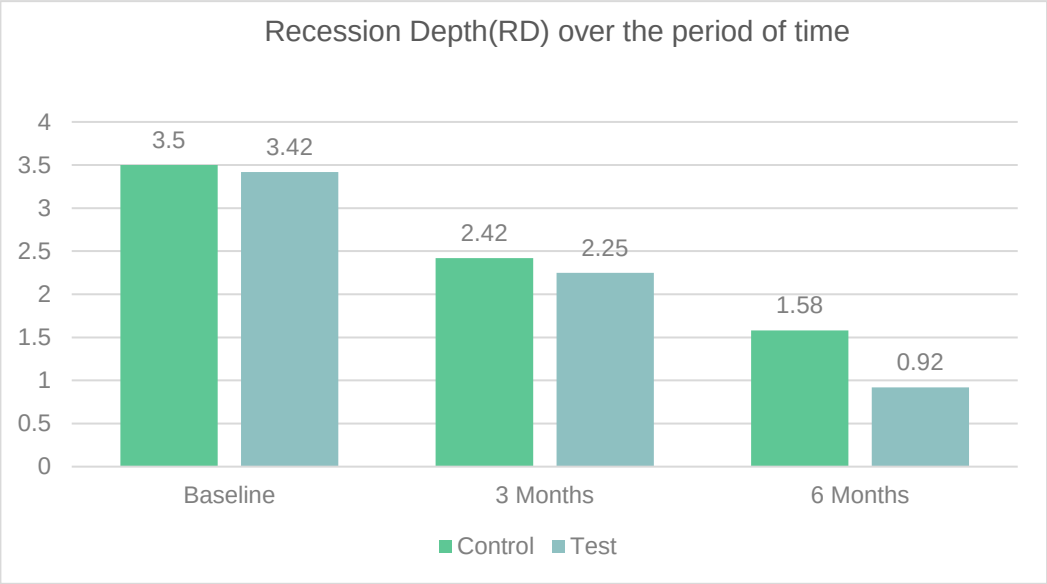


Table 2A: Intergroup comparison of Width of Keratinised Gingiva (WKG) (in mm) of control and test group over a period of time					
Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	2.00	.739	.161**
	TEST	12	2.42	.669	
3 Months	CONTROL	12	2.92	.793	**.017***
	TEST	12	3.83	.937	
6 Months	CONTROL	12	3.08	.669	**.002***
	TEST	12	4.00	.603	

** Non-Significant difference
*Significant difference

Table 2B. Intragroup comparison of Width of Keratinised Gingiva (WKG) (in mm) of control and test group over a period of time									
CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	2.00	.739	-	Baseline	12	2.42	.669	-
Baseline vs 3 Months	12	0.92	.289	**0.035***	Baseline vs 3 Months	12	1.42	.619	**0.026***
Baseline vs 6 Months	12	1.08	.353	**0.008***	Baseline vs 6 Months	12	1.58	.515	**0.008***
3 months vs 6 months	12	0.16	.389	1.000**	3 months vs 6 months	12	0.17	.369	1.000**

** Non-Significant difference
* Significant difference

Graph 2: Intergroup comparison of Width of Keratinised Gingiva (WKG) (in mm) of control and test group over a period of time

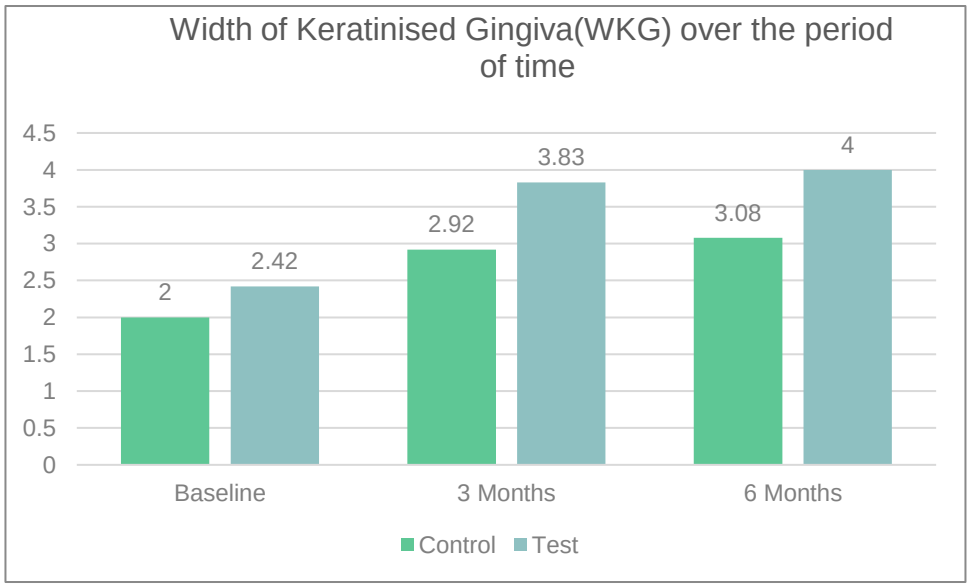


Table 3A: Intergroup comparison of Clinical Attachment Level(CAL)(in mm) of Control and Test group over a period of time					
Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	5.42	1.505	.223**
	TEST	12	4.83	.577	
3 Months	CONTROL	12	4.08	.900	.775**
	TEST	12	4.00	.426	
6 Months	CONTROL	12	3.00	.953	**.043***
	TEST	12	2.33	.492	

** Non-Significant difference
*Significant difference

Table 3B. Intragroup comparison of Clinical Attachment Level(CAL) (in mm) of Control and Test group over a period of time									
CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	5.42	1.505	-	Baseline	12	4.83	.577	-
Baseline vs 3 Months	12	1.34	.888	0.088**	Baseline vs 3 Months	12	0.83	.389	0.088**
Baseline vs 6 Months	12	2.42	1.165	**0.037***	Baseline vs 6 Months	12	2.50	.522	**0.037***
3 months vs 6 Months	12	1.08	1.084	0.104**	3 months vs 6 Months	12	1.67	.492	0.104**

**Non-Significant difference
*Significant difference

Graph 3: Intergroup comparison of Clinical Attachment Level (CAL) (in mm) of control and test group over a period of time

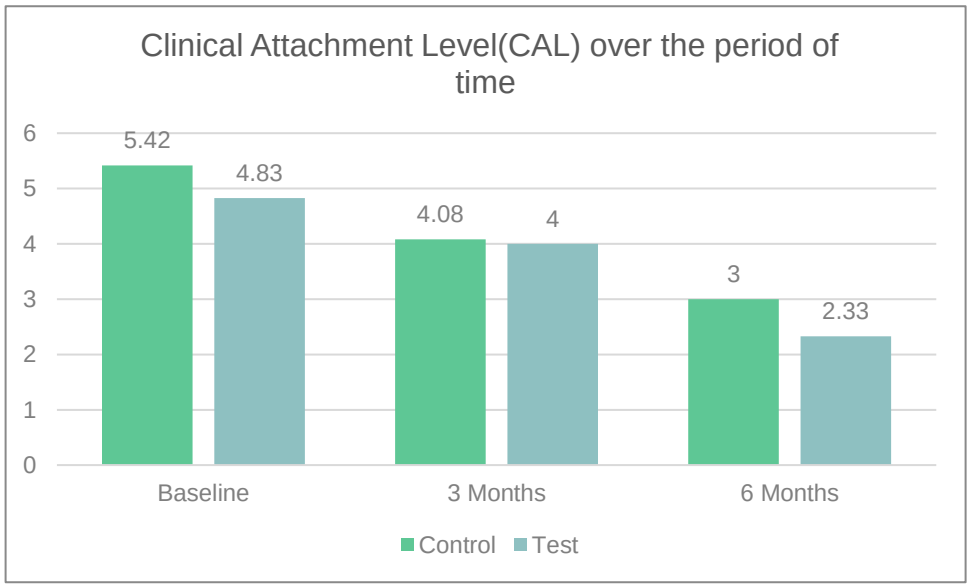


Table 4 A: Intergroup comparison of Probing Pocket Depth (PPD) (in mm) of control and test group over a period of time					
Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	1.92	.996	.137**
	TEST	12	1.42	.515	
3 Months	CONTROL	12	1.75	.452	1.000**
	TEST	12	1.73	.451	
6 Months	CONTROL	12	1.50	.522	.223**
	TEST	12	1.25	.420	

**Non-significant difference

Table 4B. Intragroup comparison of Probing Pocket Depth (PPD) (in mm) of control and test group over a period of time

CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	1.92	.996	-	Baseline	12	1.42	.515	-
Baseline vs 3 Months	12	0.17	.835	0.088**	Baseline vs 3 Months	12	-0.33	.492	0.088**
Baseline vs 6 Months	12	0.42	.793	0.338**	Baseline vs 6 Months	12	0.17	.389	0.315**
3 Months vs 6 Months	12	0.25	.622	0.298**	3 months vs 6 Months	12	0.48	.522	0.275**

**Non-significant difference

Graph 4: Intergroup comparison of Probing Pocket Depth (PPD) (in mm) of control and test group over a period of time

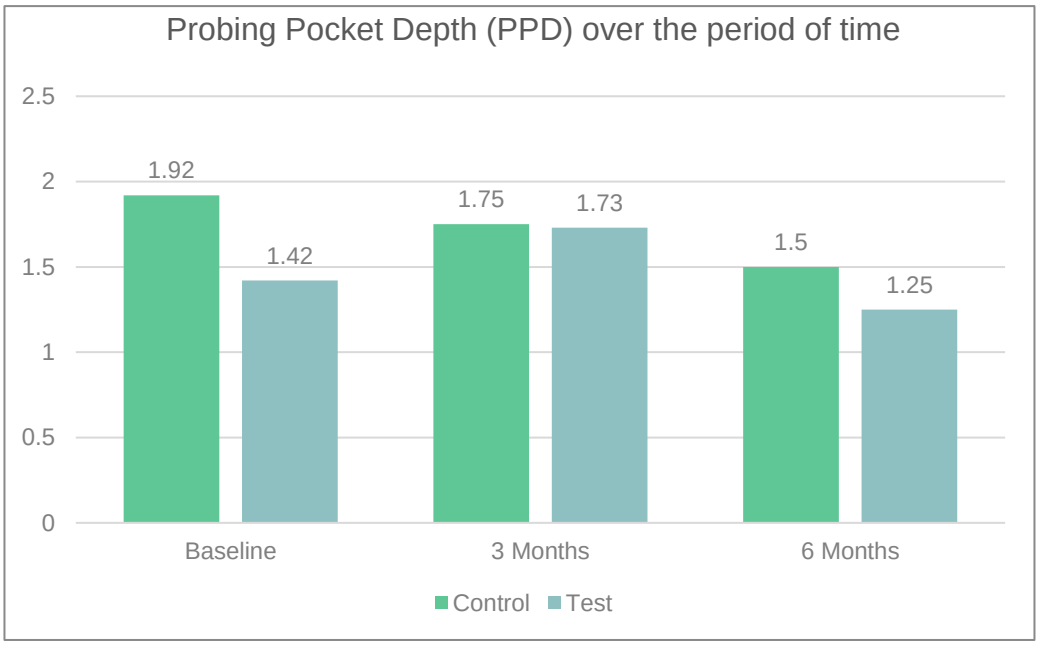


Table 5A: Intergroup comparison of Gingival Biotype (in mm) of control and test group over a period of time					
Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	1.33	.492	.143**
	TEST	12	1.08	.289	
3 Months	CONTROL	12	1.25	.306	.123**
	TEST	12	1.30	.496	
6 Months	CONTROL	12	1.35	.452	**.042***
	TEST	12	1.75	.520	

**Non-Significant difference
*Significant difference

Table 5B. Intragroup comparison of Gingival Biotype of control and test group (in mm) over a period of time									
CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	1.33	.492	-	Baseline	12	1.08	.492	-
Baseline vs 3 Months	12	0.08	.210	.345**	Baseline vs 3 Months	12	0.22	.020	.345**
Baseline vs 6 Months	12	0.02	.452	**.001***	Baseline vs 6 Months	12	0.38	.520	**.001***
3 Months vs 6 Months	12	0.10	.335	**.001***	3 Months vs 6 Months	12	0.45	.492	**.001***

** Non-Significant difference
*Significant difference

Graph 5: Intergroup comparison of Gingival Biotype (in mm) of control and test group over a period of time

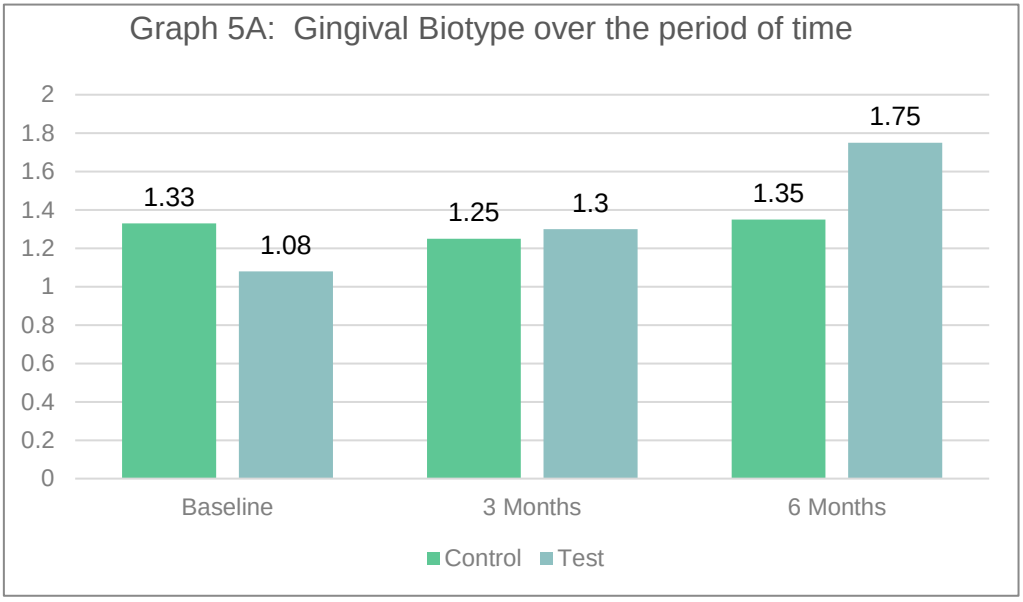


Table 6A: Intergroup comparison of Plaque Index (PI) of control and test group over a period of time					
Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	2.05	.507	.802**
	TEST	12	2.33	.424	
3 Months	CONTROL	12	1.72	.566	.076**
	TEST	12	1.47	.609	
6 Months	CONTROL	12	1.65	.591	**.002***
	TEST	12	1.08	.280	

** Non-Significant difference
*Significant difference

Table 6B. Intragroup comparison of Plaque Index (PI) of control and test group over a period of time									
CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	2.05	.507	-	Baseline	12	2.33	.424	-
Baseline vs 3 Months	12	0.30	.566	**0.020***	Baseline vs 3 Months	12	0.86	.609	**0.002***
Baseline vs 6 Months	12	0.40	.591	**0.030***	Baseline vs 6 Months	12	1.25	.280	**0.001***
3 Months vs 6 Months	12	0.07	.526	0.123**	3 Months vs 6 Months	12	0.39	.012	**0.001***

** Non-Significant difference
* Significant difference

Graph 6: Intergroup comparison of Plaque Index (PI) of control and test group over a period of time

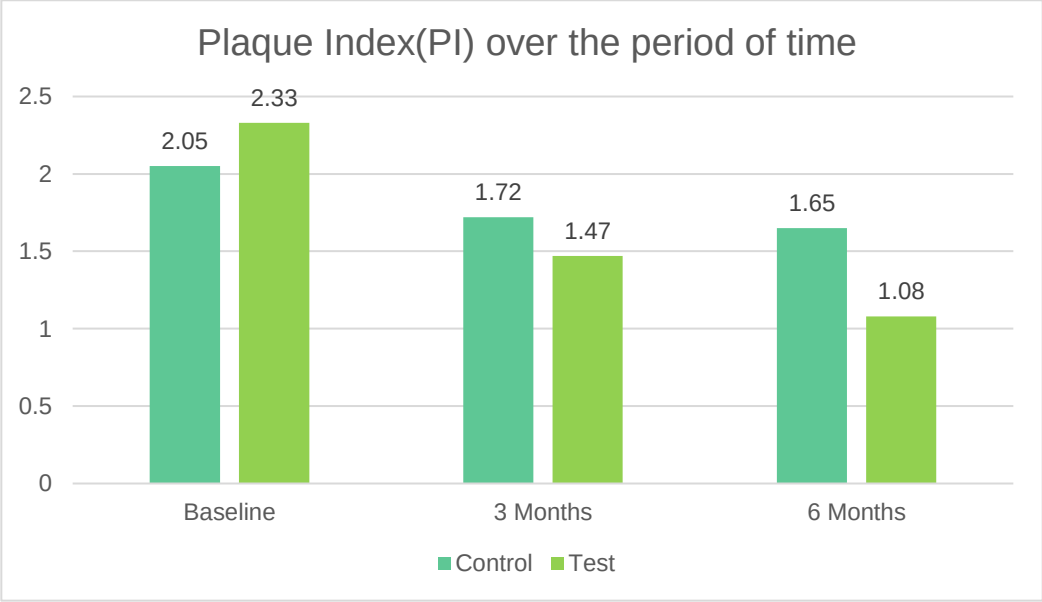


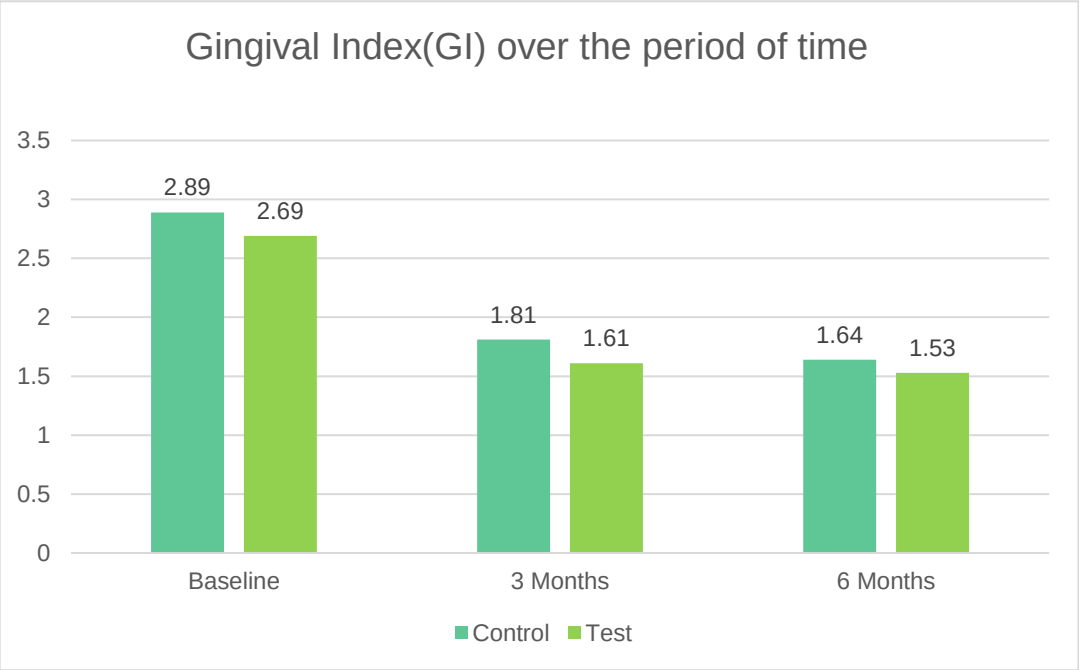
Table 7A: Intergroup comparison of Gingival Index (GI) of control and test group over a period of time					
Period	Groups	N	Mean	Std. Deviation	p-value
Baseline	CONTROL	12	2.89	.399	1.000**
	TEST	12	2.69	.398	
3 Months	CONTROL	12	1.81	.467	.147**
	TEST	12	1.61	.645	
6 Months	CONTROL	12	1.64	.683	.483**
	TEST	12	1.53	.654	

** Non-Significant difference

Table 7B. Intragroup comparison of Gingival Index (GI) of control and test group over a period of time									
CONTROL					TEST				
Period	N	Mean	Std. Deviation	p-value	Period	N	Mean	Std. Deviation	p-value
Baseline	12	2.89	.399	-	Baseline	12	2.69	.398	-
Baseline vs 3 Months	12	1.08	.467	**0.03***	Baseline vs 3 Months	12	1.08	.645	**0.004***
Baseline vs 6 Months	12	1.28	.683	0.245**	Baseline vs 6 Months	12	1.16	.654	0.059**
3 Months vs 6 Months	12	0.17	.136	**.002***	3 Months vs 6 Months	12	0.08	.082	**0.005***

** Non-Significant difference
*Significant difference

Graph 7: Intergroup comparison of Gingival Index (GI) of control and test group over a period of time



DISCUSSION

DISCUSSION

The current RCT was done to examine the relative efficacy of a CAF combined with FGF 2 impregnated bioresorbable collagen membrane and a CAF combined with a bioresorbable collagen membrane for managing the recession. These defects were chosen due to their potential for complete root coverage in cases with minimal tissue loss.[31] Based on specified inclusion criteria 24 sites were randomly divided in two groups either CAF with bioresorbable collagen membrane (Group A- control group) or CAF with FGF-2 impregnated bioresorbable collagen membrane (Group B- test group). Six months postoperative protocol was followed in this study to examine the clinical benefits of the procedures. All clinical parameters i.e., RD, WKG, CAL, PPD, Gingival biotype (GB), PI, GI were calculated at baseline as well as 3 and 6 months.

The baseline RD demonstrated comparable values among group A and group B with no statistically significant difference, ensuring a uniform starting point. At 3 months, both control (2.42 ± 0.669 mm**)** and test group (2.25 ± 0.452 mm) showed a reduction in RD, the variation among them was not statistically significant(p=.482). Although, by 6 months, test group (0.92 ± 0.515 mm) demonstrated a significantly greater decrease in RD in comparison to the group B (1.58 ± 0.793 mm) (p=.026). This indicates that the application of an FGF-2 impregnated bioresorbable collagen membrane led to superior results in RD over time, highlighting its potential efficacy in periodontal regeneration. These results suggest that while the control group experienced more rapid initial improvement, the test group demonstrated a prolonged healing effect, potentially supporting its long-term regenerative benefits. These results aligned with *Chandra et al.*,[21] *Rampalli et al.*,[26] where a statistically significant reduction of recession depth was achieved and stayed consistent throughout the duration of the study. FGF-2 promotes cell proliferation, revascularization and facilitate healing by stimulating mesenchymal stem cell growth and biochemical functions.

Intragroup analysis in control group showed decrease in RD between baseline to 3 months by 1.08 ± 0.289 mm, although the change failed to demonstrate statistical significance(p=.557). Between baseline and 6 months in RD reduction of $1.50 \pm .674$ mm, which achieved clinically significant value(p=0.026). Similar trend was noted in the FGF-2 group ($1.92 \pm .515$ mm) (p=.026). Additionally, the RD reduction between 3 and 6 months (1.33 ± 0.651 mm) exceeded in the group B than that in the other group A (0.84 ± 0.515 mm). This continued RD reduction in the test group—may reflect the ongoing biological action of growth factors, which promote fibroblast proliferation, angiogenesis,

and extracellular matrix deposition. These results align with the findings of *Rampalli et al.,*[26] *Pradhan et al.*[27] *Mahajan et al.,*[32] who documented enhanced periodontal regeneration over similar follow-up periods.

The baseline WKG was comparable between groups. At the 3-month mark, the test group demonstrated much significant gain in WKG than the control group (3.83 ± 0.937 mm**,** 2.92 ± 0.793mm**,** p=0.017, as listed). The test group exhibited a significantly superior gain in WKG relative to the control group ($4.00 \pm .603$mm**,** p=.002**,** 3.08 ± 0.669 mm**,** p=.002, respectively) at 6 months. These outcomes imply that FGF-2 impregnated bioresorbable collagen membrane effectively enhanced WKG over time. The current findings are consistent with those reported by *Chandra et al.,*[21] *Rampalli et al.,*[26] where a statistically significant improvement was reflected by enhancement in WKG and corresponding reduction in RD by 3 months follow up, with these outcomes remaining consistent throughout the study period. FGF-2 promotes the proliferation of periodontal ligament (PDL) cells while initially limiting their maturation into osteoblasts and cementoblasts. As healing progresses, these PDL cells gradually undergo differentiation, supporting significant regeneration of periodontal soft tissues. Additionally, the early development of connective tissue originating from the existing PDL may help in preventing the apical migration of gingival epithelium as well as aid in preserving gingival tissue height.

From baseline the test group revealed significant improvement in the WKG over 3 months period (1.42 ± 0.619 mm, p=.026), and subsequently at 6 months ($1.58 \pm .515$ mm, p=.008), when compared with control group. However, between 3 and 6 months, both groups exhibited minimal and equal WKG gains (control 0.16 ± 0.389 mm, p=1.000, test 0.17 ± 0.369 mm, p=1.000). This is in alignment with the study performed by *Agarwal et al.,*[1] *Rampalli et al.,*[26]*, Potharaju et al.,*[28] in which similar results were found over similar time period using collagen membranes. These findings suggest that most WKG improvement occurred within the first 3 months, with the group B achieving a greater overall increase.

The baseline CAL was comparable between groups. At 3 months, test and control group showed similar improvement (4.00 ± 0.426 mm, 4.08 ± 0.900 mm, p=0.775). However, by 6 months, the test group ($2.33 \pm .492$ mm, p=0.043), achieved a significantly greater CAL gain in comparison to control group ($3.00 \pm .953$mm, p=0.043). These findings suggest that the FGF-2 impregnated collagen membrane effectively enhanced clinical attachment over time, as per the study by *Cha JK et al.,*[34] on dogs. There is lack of data regarding this in humans, however this can be attributed to the biological

properties of FGF-2 as it enhances periodontal regeneration by promoting angiogenesis, increasing the population of periodontal ligament cells, and promoting the development of new cementum and attachment of connective tissue. As far as we are aware, this is a novel study to compare the role of FGF-2 impregnated bioresorbable membrane for soft tissue regeneration. The intragroup analysis demonstrated a steady gain in CAL within both groups across the 6-month period. CAL improved between baseline to 3 months ($1.34 \pm .888$ mm) ($p = .088$) and significantly between baseline and 6 months (2.42 ± 1.165 mm, ($p = 0.037$). The test group showed similar trends, with CAL improving from baseline to 6 months 2.50 ± 0.522 mm ($p = 0.037$). Similar observations were made in the study carried out by *Pradhan et al*[27]*., Potharaju et al.,*[28] where similar results were found using collagen membranes over a similar follow up period.

Both groups showed minimal changes in PPD over time, with no statistically significant differences at any interval. While the test group exhibited a greater reduction from 3 to 6 months (1.73 ± 0.451 to 1.25 ± 0.420), overall changes remained insignificant($p=0.223$), suggesting neither treatment had a superior impact on PPD over the 6-month period. This aligns with the study by *Chandra et al.,*[21] *Rampalli et al.,*[26] who showed no effect on probing depth reduction. In the control group, PPD reduction at 3 month interval was 0.17 ± 0.835 mm with an additional decreased by $.42 \pm .793$ mm at 6 months. The test group presented a baseline value of 1.42 ± 0.515 mm, reducing by -0.33 ± 0.492 mm at 3 months, indicating healing and improved tissue attachment. Between baseline and 6 months the FGF-2 group had a value of $.17 \pm 0.389$ mm. Despite these variations being not statistically significant, they indicate stable and shallow periodontal pockets throughout the period. This suggested effective maintenance of periodontal health rather than active pocket. Similar outcomes have been suggested by *Potharaju et al.,*[28] *Mahajan et al.,*[32] *Bhaskar et al.,*[36] where changes in PPD were minimal and statistically insignificant over similar follow-up periods.

The baseline gingival biotype was comparable between groups, with no significant changes at 3 months. However, by 6 months, the test group exhibits significantly greater improvement (1.75 ± 0.520mm**,** $p=0.042$), suggesting that the FGF-2 impregnated bioresorbable collagen membrane effectively enhanced gingival biotype over time. This aligns with study by *Chandra et al.,*[21] *Rampalli et al.,*[26] which showed significant improvement in gingival biotype. Comparable results were demonstrated in the work of *Mishra et al.,*[30] who showed significant improvement at 6 months interval ($p < .001$). Intragroup comparison revealed progressive improvement in gingival biotype within both the groups under study. In the control group slight improvement was observed

between baseline to three months (0.08 ± 0.210) (p =.345) and baseline to 6 months ($.02 \pm .452$), (p=.001). The statistical change from 3 to 6 months (0.10 ± 0.335, p = 0.001) were significant, suggested that most of the biotype thickening occurred later in the healing phase. The test group showed more pronounced increase in biotype. Statistically significant gain was seen between 3 and 6 months (0.45 ± 0.492, p = 0.001). This greater gain in the test group indicates enhanced soft tissue maturation when FGF-2 is incorporated, likely due to its role in stimulating fibroblast proliferation, neovascularization, and extracellular matrix synthesis. Parallel findings were found in a study done by *Pradhan et al*[27], *Mahajan et al.*[32] using collagen membrane for a similar time period.

The intergroup comparison of PI revealed a steady reduction in both groups over time, with the test group consistently showing lower scores. At baseline PI was comparable between control (2.05 ± 0.507) and test (2.33 ± 0.424) groups (p = 0.802). By 6 months, a statistically significant difference was noted (control: 65 ± 0.591 vs. test: 1.08 ± 0.280; p = 0.002). Statistically significant difference was not seen in the GI at any point of time, both groups showed clinical improvement 6 months from baseline. In intragroup comparison, both group A and group B showed significantly relevant decline in GI from baseline to 3 months ($1.08 \pm .645$, p = .03 and $1.08 \pm .467$, p=.004, respectively), indicating early improvement in gingival health. However, between baseline to 6 months no statistically significant values were noted in both groups. Based on existing research, there appears to be a lack of studies that have specifically evaluated changes in plaque and gingival index using FGF-2 impregnated collagen membrane. However same data was observed in studies by *Potharaju et al.,*[28] *Mahajan et al.,*[32] using bioresorbable collagen membrane for similar time period.

Both the study groups exhibited a statistically significant decrease in RD across the evaluation period. The WKG also increased significantly in both groups, with the test group showing a greater gain. For CAL, both groups exhibited statistically significant gains over time, with the test group demonstrating a more pronounced improvement. Variations in PPD were statistically significant in both groups, though minimal in magnitude. The test group initially showed a slight increase at 3 months before reducing at 6 months, suggesting a transient inflammatory response followed by stabilization. Overall, both treatments maintained shallow pockets indicative of healthy periodontal conditions. The study groups exhibited statistically significant enhancement in gingival biotype over time, with the test group exhibiting a greater shift toward a thicker biotype by 6 months, indicating enhanced soft tissue outcomes with the addition of FGF-2.

Recent evidence by *Yang et al.,*[23] reinforces the therapeutic outcome of utilizing CAF in conjunction

via concentrated growth factor (CGF) for managing gingival recession classified as Class I and II. These findings collectively support the enhanced regenerative potential of combining CAF with FGF-2 impregnated collagen membrane, promoting improved soft tissue outcomes compared to CAF with collagen membrane alone. There was no evidence of toxicity to FGF-2 impregnated bioresorbable collagen membrane. FGF-2 facilitates soft tissue healing through the formation of periosteum, enhancement of local neovascularization, and increased cellular activity. It also supports the development of new attachment to the root surface via cementum formation, collectively aiding in effective soft tissue regeneration and root coverage.[21]

Based on available evidence, this appears to be one of the first study of its kind comparing FGF-2 impregnated collagen membrane with other bioresorbable collagen membrane. To reiterate, the outcome of this study suggested that the use of FGF-2 impregnated bioresorbable collagen membrane may offer enhanced outcomes in clinical parameters such as RD, WKG, CAL, PPD, gingival biotype, PI and GI when compared to collagen membrane alone, in the intervention of localized gingival recession.

SUMMARY

SUMMARY

Gingival recession, characterized by apical migration of marginal gingiva beyond the cementoenamel junction, remains a challenging concern in periodontal therapy. Although numerous periodontal plastic techniques have been used to manage this condition, recent attention has shifted towards the use of biologically active agents like growth factors to improve regenerative outcomes. Among these, FGF-2 has been identified as a reliable growth factor due to its ability to stimulate cell growth, angiogenesis, and periodontal regeneration. Collagen membranes serve as an effective carrier for FGF-2, promoting localized delivery and sustained release at the surgical site. The current randomized clinical study was done to evaluate and compare the effectiveness of a CAF combined with a bioresorbable membrane infused with FGF-2 versus CAF used with a collagen membrane alone for the management of gingival recession. Twenty-four sites were allocated randomly to the both the groups and monitored over a six-month follow-up duration.

Summarizing the results of our study-

- RD demonstrated a significant decrease through both intragroup and intergroup comparisons. Group B, however, exhibited better clinical results over the 6-month period, suggesting an additional advantage with the use of FGF-2.
- WKG showed significant improvement within and between groups, with the test group showed a notable increase from baseline to 6 months, highlighting the effectiveness of FGF-2.
- CAL improved in within and between groups, however the test group had significant gain in CAL at 6 months from baseline as compared to non-FGF 2 group, suggesting added benefits of FGF-2.
- PPD decreased modestly in within and between groups with no significant difference in test and control group over a 6 months period.
- Both intergroup and intragroup showed statistically significant difference in gingival biotype over 6 months follow up period, group B demonstrated more favorable outcomes compared to the control group indicating enhanced benefit of FGF-2.
- The PI showed significant reduction in group A and B at 3 months and 6 months from baseline thorough intergroup comparison. The difference in GI was non-significant between the test as well as control groups, however both groups demonstrated significant decrease in PI and GI via

baseline to 3 and 6 months. The intragroup comparison of PI and GI showed non- significant difference in both test and the control group across the intervals from baseline to 3 months and baseline to 6 months.

- The FGF-2 group demonstrated early and sustained soft-tissue regeneration, including enhanced gingival thickness and improved clinical attachment. All subjects exhibited normal healing, and no unfavorable reactions to the FGF-2 delivery system were observed. Although the findings are promising, the study has limitations, such as modest sample group and the absence of histological evaluation, and a short follow-up period. Further studies with larger cohorts and extended monitoring are necessary to validate the stability and consistency of the regenerative outcomes associated with FGF-2.

To reiterate, while both treatments proved effective, the addition of FGF-2 to a collagen membrane in conjunction with CAF may offer superior clinical benefits in managing localized gingival recession, supporting its potential role in future periodontal regenerative therapies.

CONCLUSION

CONCLUSION

Achieving consistent and esthetic root coverage is a key objective in periodontal therapy. Guided tissue regeneration-based interventions for gingival recession have shown good outcomes and is drawing clinical attention. Few studies have concentrated on the use growth factors impregnated bioresorbable collagen membrane for root coverage on human subjects. Given the study's limitations, it may be concluded that both therapeutic approaches—CAF with collagen membrane and CAF with FGF-2 impregnated collagen membrane—were better in addressing the recession defects. However, the addition of FGF-2 resulted in greater improvements in RD, WKG, CAL, gingival biotype indicating enhanced regenerative potential. These findings suggest that FGF-2 may be a valuable adjunct in periodontal plastic surgery, though further long-term and histological studies are warranted to confirm its clinical efficacy and stability.

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ANNEXURES

ANNEXURE 1

THESIS CASE HISTORY

DEPARTMENT OF PERIODONTICS AND ORAL IMPLANTOLOGY

SANTOSH DENTAL COLLEGE, GHAZIABAD

TOPIC - A COMPARATIVE EVALUATION OF THE EFFICACY OF RECOMBINANT HUMAN FIBROBLAST GROWTH FACTOR 2 (FGF-2) IMPREGNATED BIORESORBABLE COLLAGEN MEMBRANE AND BIORESORBABLE COLLAGEN MEMBRANE IN THE MANAGEMENT OF MILLER'S CLASS I & II GINGIVAL RECESSION – A RANDOMISED CONTROLLED STUDY

NAME OF THE PATIENT:

AGE/SEX:

OPD NO:

DATE:

OCCUPATION:

CHIEF
COMPLAINT:

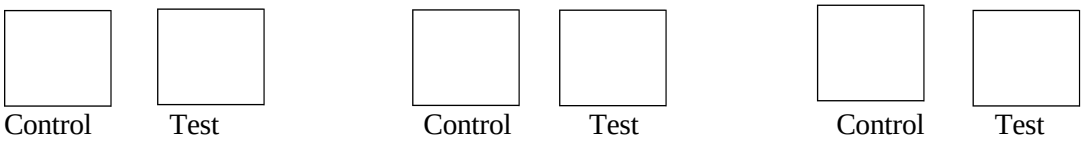
DIAGNOSIS:

CLINICAL PARAMETERS

Recession Depth(RD)

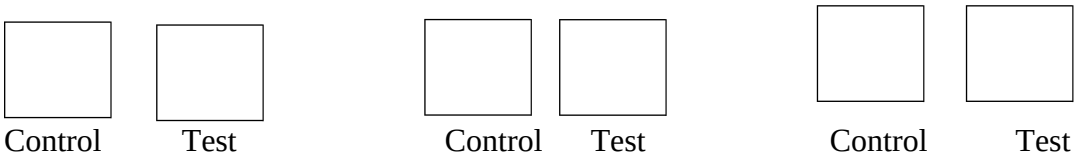
☐	☐	☐	☐	☐	☐
Control	Test	Control	Test	Control	Test
BASELINE		3 MONTHS		6 MONTHS	

Width of Keratinised Gingiva (WKG)



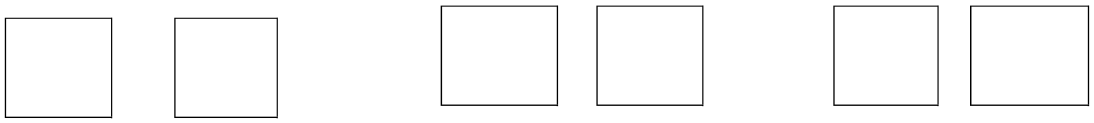
BASELINE 3 MONTHS 6 MONTHS

Probing Pocket Depth (PPD)



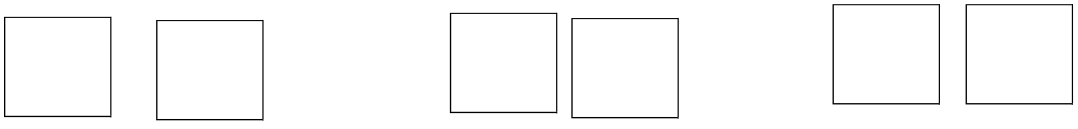
BASELINE 3 MONTHS 6 MONTHS

Clinical Attachment Level (CAL)



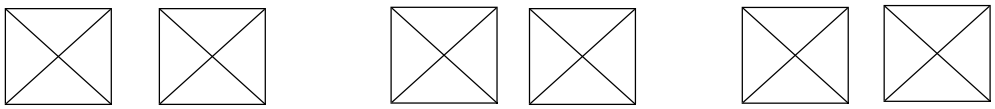
BASELINE 3 MONTHS 6 MONTHS

Gingival Biotype



BASELINE 3 MONTHS 6 MONTHS

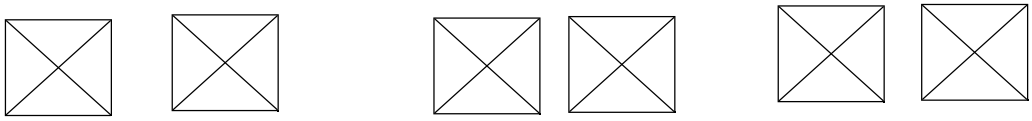
Plaque Index (PI)



Control Test Control Test Control Test

BASELINE 3 MONTHS 6 MONTHS

Gingiva Index (GI)



Control Test Control Test Control Test

BASELINE 3 MONTHS 6 MONTHS

Signature

Head of Department

ANNEXURE 2

CONSENT FORM

SANTOSH
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

Department of Periodontics and Oral Implantology

INFORMED CONSENT FORM

I _____,age____son/daughter of R/O_____gives full consent for the examination, investigation and the treatment, without any compulsion of any kind.

1. Doctor has fully explained to me the purpose of the procedure(s), the predictable and unpredictable consequences of the procedure, drug administered if any including the use of local anaesthesia , and has also informed me of expected benefits and complications (from known and unknown causes), discomforts and risks that may arise as well as possible alternatives to the proposed treatment including no treatment. The risks of no treatment have also been discussed. I have been given an opportunity to ask questions and all my questions have been answered fully and satisfactorily.

2. I understand that during the course of the procedure(s), unforeseen conditions may arise which necessitates procedures different from those contemplated. I, therefore, consent to the performance of additional procedures that the above-named dentist or his/her associate may consider necessary.

3. I acknowledge that no guarantee or assurances have been made to me concerning the results intended from the procedure(s).

4. No identity lies with the doctor in case the treatment is discontinued or the outcome is not as predicted.

5. I confirm that I have read and fully understand the above and that all blank spaces have been completed prior to my signing. I give my consent that this record can be used for research, education, training &upliftment of the dental profession.

Signature of patient Date:

HEAD OF DEPARTMENT

ANNEXURE 3

सन्तोष डेन्टल कॉलेज

प्रताप विहार, गाजियाबाद

सहमति पत्र

1. मैं .....पुत्र/पत्री.....निवासी.....
..... अपने ऊपर किये जाने वाले निरीक्षण/ परीक्षण, चिकित्सीय सलाह/पद्धति की पूर्ण सहमति देता/देती हुं।

2. मुझे चिकित्सा प्रणाली और चिकित्सा के उपरान्त होने वाले संभावित नतीजों के बारे में दंत चिकित्सक के द्वारा अच्छी तरह समझाया गया है।

3. मुझे चिकित्सा के दौरान अथवा उसके उपरांत होने वाली संभावित/ अप्रत्याशित हानियों, इलाज के समय उपयुक्त होने वाली दवा व उसके प्रयोग के बारे में भी अच्छी तरह बताया गया है।

4. रोगी के द्वारा चिकित्सा के बीच में ही छोड़कर जाने अथवा चिकित्सा के उपरान्त परिणाम के उम्मीद के अनुसार न आने पर, चिकित्सक की जिम्मेदारी नहीं होगी।

5. मैं पुनः अपनी सहमति देता हूँ कि इस रिकार्ड को भविष्य में चिकित्सीय शोध, प्रशिक्षण एवं चिकित्सा प्रणाली के उत्थान के लिये प्रयोग किया जा सकता है।

तारीखः

रोगी के हस्ताक्षर

ANNEXURE 4

SANTOSH
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F. No. SU/2023/2480[13] Dated: 26.09.2023

Subject: Grant of Ethical Clearance for Thesis Protocol Topic "A comparative evaluation of the efficacy of recombinant human fibroblasts growth factor 2(FGF-2) impregnated bioresorbable collagen membrane along with bioresorbable collagen membrane in the management of miller's class I and II Gingival Recession - A Randomised Controlled Study", submitted by **Dr. KAVITA SINGH,** MDS student of Batch 2022-2023, Department of **PERIODONTOLOGY**.

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled "A comparative evaluation of the efficacy of recombinant human fibroblasts growth factor 2(FGF-2) impregnated bioresorbable collagen membrane along with bioresorbable collagen membrane in the management of miller's class I and II Gingival Recession - A Randomised Controlled Study", **Dr. KAVITA SINGH** is informed that the Thesis Protocol submitted by him/her was considered by the **Screening Committee** of the Santosh Dental College & Hospital in its meetings held on 07.02.2023 & 08.02.2023. The recommendations of the **Screening Committee** were considered in detail by the Institutional **Ethics Committee** in its meeting held on **23.09.2023** and the same was **approved** by the **Ethics Committee**.

He /She is informed accordingly for further necessary action.

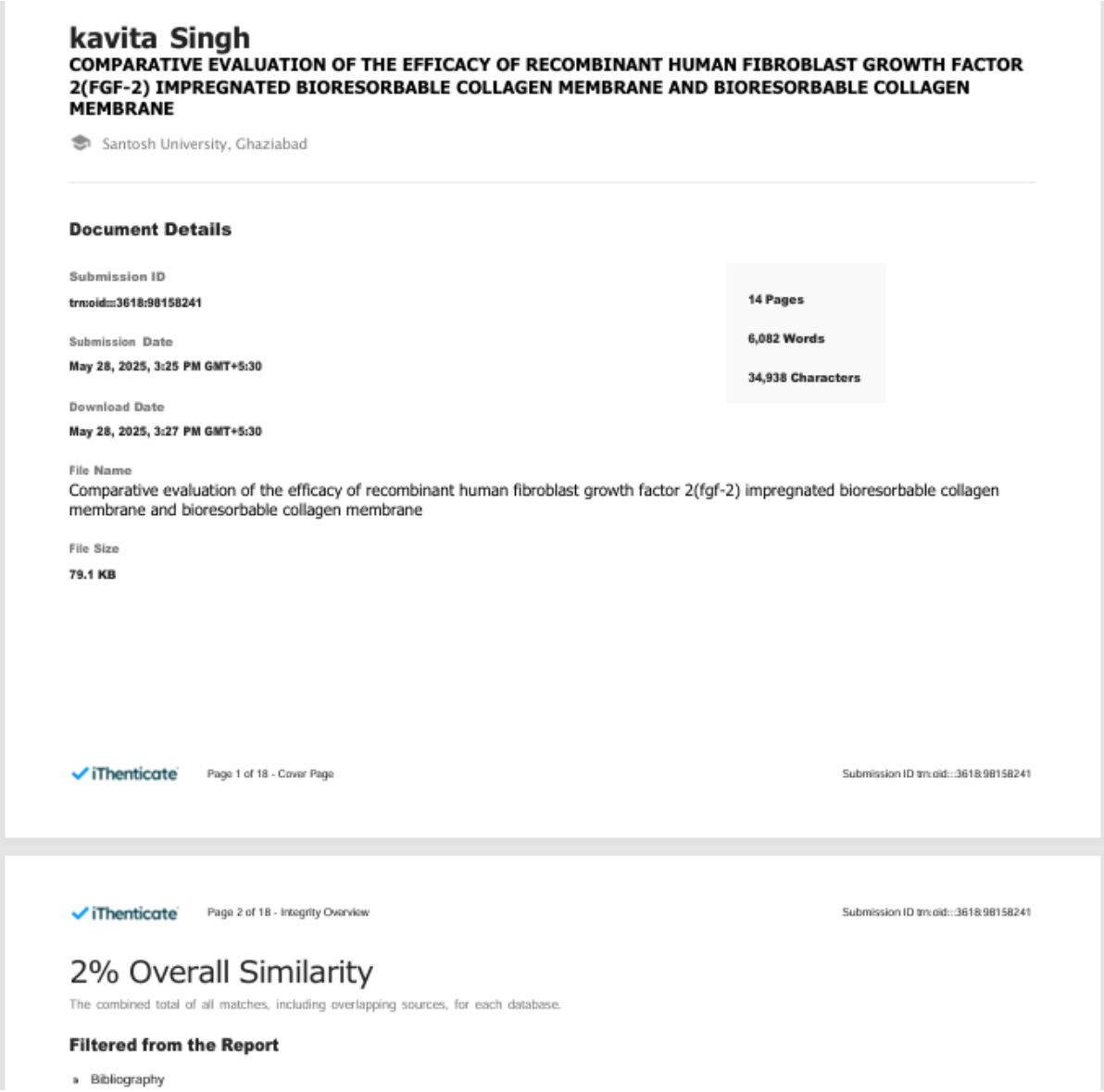
[DR. NARESH SHARMA]
REGISTRAR

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, (U.P.) INDIA

Dr. KAVITA SINGH
MDS student of batch 2022-2023
Department of PERIODONTOLOGY
Email: kavita.rathore95@gmail.com

Copy to:
1. The Vice Chancellor
2. The Dean, SDC&H
3. The Dean – Research
4. The Dean – Academics
5. The Director - IQAC
6. **Dr. Shweta Bali** (Guide)
7. HOD of **PERIODONTOLOGY**

ANNEXURE 5



kavita Singh

COMPARATIVE EVALUATION OF THE EFFICACY OF RECOMBINANT HUMAN FIBROBLAST GROWTH FACTOR 2(FGF-2) IMPREGNATED BIORESORBABLE COLLAGEN MEMBRANE AND BIORESORBABLE COLLAGEN MEMBRANE

Santosh University, Ghaziabad

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Comparative evaluation of the efficacy of recombinant human fibroblast growth factor 2(fgf-2) impregnated bioresorbable collagen membrane and bioresorbable collagen membrane

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